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Decision and Emergency Order Suspending Registrations for the Forest, Rights-of-Way, and Pasture Uses of 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T)

(U.S.) Environmental Protection Agency
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A suspension order is an agency determination that is necessary to prevent an imminent hazard during the time required to cancel registration or classification proceedings (the Rebuttable Presumption Against Registration process--RPAR). This determination is made under Section 6(B)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This notification immediately suspends the registration of the chemical under Agency review, prohibiting its use, sale, or distribution during the cancellation or classification change proceedings. Upon resolution of the proceedings, a final Agency regulatory decision on the chemical is made. A hearing may be held on the suspension order in accordance with Subchapter II of Title 5 of the United States Code.

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DECISION AND EMERGENCY ORDER SUSPENDING REGISTRATIONS FOR THE FOREST, RIGHTS-OF-WAY, AND PASTURE USES OF 2,4,5-TRICHLOROPHENOXYACETIC ACID (2,4,5-T)

NOTICE OF INTENT TO CANCEL THE FORESTRY, RIGHTS-OF-WAY AND PASTURE REGISTRATIONS OF PESTICIDE PRODUCTS CONTAINING 2,4,5-T

SUSPENSION ORDER FOR 2,4,5-T

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D. C. 20460

EPA/SPRD -80/103

Office of Pesticide Programs

February 28, 1979

Decision and Emergency Order Suspending Registrations for the Forest, Rights-of-way, and Pasture Uses of 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T)

I. INTRODUCTION

During the past ten months, the Agency has been gathering information about 2,4,5-T through its Rebuttable Presumption Against Registration (RPAR) process in order to decide whether registration of this pesticide should be continued (43 FR 17116, April 21, 1978). This review was prompted by studies showing that 2,4,5-T and/or its dioxin contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) */, caused reproductive and oncogenic effects in test animals. During the public debate initiated by the 2,4,5-T RPAR, the Agency received reports that women living in the vicinity of Alsea, Oregon, had miscarriages shortly after 2,4,5-T was sprayed in the forest areas where they reside. The Agency investigated the circumstances surrounding these reported

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*/ Current methods for manufacturing 2,4,5-T produce TCDD as a by-product of the manufacturing process. Although 2,4,5-T manufacturers attempt to remove this contaminant, TCDD cannot be completely removed. An EPA contract laboratory has measured the TCDD content in 16 recently produced commercial samples of technical grade 2,4,5-T from five different manufacturers. The contractor reported that the TCDD content in these samples ranged from not detectable to 0.025 ppm (limit of detection: 0.01 ppm) [excluding higher values that the contractor reported as doubtful]. Therefore, because TCDD is present as a low-level contaminant in commercial samples of 2,4,5-T, references in this document to "2,4,5-T" or the "pesticide product" mean 2,4,5-T that is contaminated with TCDD.

miscarriages and compared the frequency of miscarriage in the Alsea area with comparable data from a control area. The Agency has concluded that the use of 2,4,5-T over a six-year period in the Alsea area was related to a statistically significant increase in the frequency of miscarriages by women residents of the area, and that these miscarriages occurred shortly after the use of 2,4,5-T in the area where these women lived.

Based on this and other information detailed below, I am ordering several emergency suspensions under FIFRA Section 6(c). These emergency suspensions immediately halt the distribution, sale, and use of 2,4,5-T for forestry, rights-of-way, and pastures until the completion of further administrative proceedings.**/ I am ordering emergency suspension of these uses because I find that they pose an "imminent hazard" to humans and because I also find that an "emergency" exists because there is not enough time to complete a suspension hearing before the next spraying season.

**/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

II. LEGAL AUTHORITY

A. Standards for Maintaining a Registration

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) [7 U.S.C. 136 et seq.], a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires (among other things) that the pesticide perform its intended function without "unreasonable adverse effects" on the environment [FIFRA Section 3(c)(5)]. "Unreasonable adverse effect on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [FIFRA Section 2(bb)]. In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of the use. The burden of proving that a pesticide satisfies the registration standard rests with the registrant and continues for as long as the registration remains in effect [Environmental Defense Fund v. Environmental Protection Agency, 510 F.2d 1292, 1297 (CADC, 1975); Environmental Defense Fund v. Environmental Protection Agency, 465 F.2d 528, 532 (CADC, 1972)]. Under Section 6 of FIFRA, the Administrator is required to cancel the registration, or change the classification, of a pesticide whenever he determines that the pesticide no longer satisfies the statutory standard for registration.

B. Purpose and Standard for Suspending a Pesticide

The suspension provisions in Section 6(c) of the statute give the Administrator authority to take interim action until completion of the time-consuming procedures required to reach final cancellation decisions. Under this Section, the Administrator may suspend the registrations of a product and prohibit its distribution, sale, or use during cancellation proceedings upon a finding that the pesticide poses an "imminent hazard" to humans or the environment. "Imminent hazard" is defined by the statute to mean that:

> The continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 94-135.

As discussed above, "unreasonable adverse effects on the environment" means that the risks from use of a pesticide outweigh the benefits of its use. Thus, in order to find an imminent hazard, it is necessary to find that the risks of use during the period likely to be required for cancellation proceedings appear to outweigh the benefits. The Administrator may not suspend a pesticide without having issued a notice of his intention to cancel the registration, or to change the classification, of the pesticide.

Suspension is the Administrator's tool for quickly correcting a situation which endangers public health. The courts have repeatedly held that "the function of a suspension decision is to make a preliminary assessment of evidence, and probabilities, not an ultimate resolution of difficult issues" [Environmental Defense Fund v. Environmental Protection Agency, supra, 510 F2d at 1298]. "It is enough if there is a substantial likelihood [emphasis in original] that serious harm will be experienced during the year or two required in any realistic projection of the administrative cancellation) process" [Environmental Defense Fund, Inc. v. Environmental Protection Agency, 510 F2d 1292, 1297, (D.C. Cir. 1975) quoting from Environmental Defense Fund, Inc. v. Environmental Protection Agency, supra, 465 F2d 540 (D.C. Cir. 1972)]. Moreover, the registrant bears the burden of proof during a suspension proceeding because, as indicated above, the burden of proof under FIFRA always resides with the proponent of registration throughout the life of a registration. [See, e.g., Environmental Defense Fund v. Environmental Protection Agency, 510 F2d at 1297; Environmental Defense Fund v. Environmental Protection Agency, supra, 465 F2d at 532.)

C. Types of Suspension Proceedings

In this order, I have begun emergency suspension proceedings. This is not the only type of suspension provided in FIFRA. Section 6(c) provides for two kinds of suspension proceedings: ordinary suspensions [FIFRA Section 6(c)(2)] and emergency suspensions [FIFRA Section 6(c)(3)]. I have chosen to discuss both kinds of suspension because the procedures applicable to each action are intertwined and because of the complexity of the suspension provision as a whole.

(1) Ordinary Suspensions

The Administrator may begin an ordinary suspension when he finds that action is required to prevent an "imminent hazard." An ordinary suspension is not effective immediately; instead, the Administrator is required to give registrants notice of his intent to suspend and to allow five days for them to request a hearing. Only a registrant may request a hearing. If a hearing is not requested within five days, the suspension order becomes final and is not reviewable by a court. If a hearing is requested, the Administrator is required to convene an expedited proceeding at which other interested persons can intervene. The sole issue at a hearing is whether an imminent hazard in fact exists. The procedures for conducting the hearing, with limited exceptions discussed below, parallel the hearing procedures for an emergency suspension. The Administrator decides whether to affirm his imminent hazard determination at the conclusion of the hearing; if he does, he issues a suspension order. This order is accompanied by a notice of intent to cancel the registration, or to change the classification, of a pesticide (if one has not previously been issued). A final order on suspension following a hearing is reviewable in the Court of Appeals.

(2) Emergency Suspensions

Before issuing an emergency suspension order, the Administrator is required to make two findings: (1) that the pesticide poses an "imminent hazard" and (2) that an "emergency" exists. An "emergency" exists when the situation "does not permit [the Administrator] to hold a hearing before suspending" [FIFRA Section 6(c)(3), 7 U.S.C. 136d(c)(3)]. The Agency interprets this statutory provision to mean that, if the threat of harm to humans and to the environment is so immediate that the continuation of a pesticide use is likely to result in unreasonable adverse effects - i.e. the risks outweigh the benefits - during a suspension hearing, the registration of any product for that use may be suspended immediately[*].

An emergency suspension order is issued without prior notice to registrants and takes effect immediately; it remains in effect until the cancellation decision if no expedited hearing is requested. If an expedited hearing is requested on the issue of imminent hazard, the emergency order continues in effect until the issuance of a final suspension order. Registrants are given five days to request an expedited hearing. The hearing stage is to begin within five days of the Agency's receipt of the hearing request. Unlike the ordinary suspension situation, no party other than the registrant and the Agency may participate in the expedited hearing on the emergency order, except to file briefs. The procedures for conducting the hearing are otherwise the same as in an ordinary suspension. For both types of suspension, the hearing is to be conducted in accordance with 5 U.S.C. Sections 554, 556, and 557 except that the presiding officer need not be a certified hearing examiner. For both types of suspension, the presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator. The Administrator shall then have seven days to issue a final order on the issue of suspension.

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[*] The term "emergency" is not defined by FIFRA, and the statute in the emergency suspension section does not specifically require the Agency to balance benefits against health and environmental risk of pesticide use. An alternative reading would be that an emergency should issue whenever a risk could result from pesticide use during the time for conducting a suspension hearing. However, for the purpose of this proceeding I have decided to consider the risks and benefits in ordering an emergency suspension, just as I balance risks and benefits in deciding whether to register a pesticide or to take the pesticide off the market through a cancellation or ordinary suspension order. FIFRA is a risk/benefit statute, and I see no reason to depart from this balancing test in issuing emergency suspension orders.

FIFRA provides for a special appeal of an emergency suspension order to the District Court. If an administrative hearing is requested, an emergency suspension order is subject to immediate review in District Court by the registrant or by other interested persons with the registrant's consent. On the other hand, if no request for a hearing before the Agency is made, the emergency order becomes final and is not reviewable by any court [FIFRA Section 6(c)(2), 6(c)(3)]. The District Court action may occur simultaneously with the suspension proceeding before the Administrator.

The District Court reviews only whether the emergency finding is supported. The standard for review by the District Court is very narrow--whether the order of suspension is "arbitrary, capricious, or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law" [FIFRA Section 6(c)(4)]. If the District

Court finds against the Agency, it may stay the suspension order until completion of the expedited suspension hearing.

The District Court order may be appealed to the Appellate Court by either the Agency or the registrant, depending on the outcome. A final order on suspension, after a hearing before the Agency, may be reviewed in the Court of Appeals on an expedited basis even though related cancellation proceedings may not have been completed.

III. SUMMARY OF FINDINGS

A. Summary of Findings on Risks

Numerous studies have clearly demonstrated that TCDD and/or 2,4,5-T contaminated with TCDDD can produce fetotoxic, teratogenic, and carcinogenic effects in experimental animals which have been exposed to these chemicals. I find that the occurrence of these effects in test animals indicates that humans who are exposed to TCDD and/or 2,4,5-T may experience comparable effects.

A recent epidemiological study reported that women living in the vicinity of Alsea, Oregon (an area where 2,4,5-T is used for forest management), have a statistically significant higher incidence of spontaneous abortions (miscarriages) than women living in a control area. Specifically, the study shows that:

(1) The spontaneous abortion index for the Alsea study area where 2,4,5-T is used is significiantly higher than the index for urban or rural control areas where there is no known use of 2,4,5-T.

(2) There is a significant increase in the spontaneous abortion index in the study area relative to the control area in the months of June and July: this increase follows by approximately two months a period in March and April when 2,4,5-T was used to control vegetation in the forested areas in which these women live.

(3) Statistical analyses of these data indicate that there is a significant correlation between the amounts of 2,4,5-T used in the study area during the spraying season and the subsequent increase in the spontaneous abortion index in the study area.

This relationship between exposure to 2,4,5-T spraying and an increased incidence of miscarriages in humans is not surprising. This is the same relationship that has been demonstrated to exist in test animals through numerous animal studies. While there are uncertainties concerning the amount of 2,4,5-T and/or TCDD to which the study area women may have been exposed and concerning the precise route (or routes) of human exposure, the statistically significant incidence of miscarriages described above makes it reasonable for the Agency to conclude that these women in the Alsea Study area were exposed to 2,4,5-T.

The Agency concludes that it is also reasonable to assume that individuals may be exposed to 2,4,5-T and/or TCDD who frequent or live in areas where 2,4,5-T is used in ways and under conditions which may cause them to experience exposure opportunities qualitatively similar to that experienced by the Study area women. The Agency has concluded that 2,4,5-T use patterns involving exposure opportunities qualitatively similar to those experienced by the Study area women are the forestry, rights-of-way, and pasture uses of 2,4,5-T. The Agency has identified pesticide applicators and persons involved in pesticide application support activities, and persons living in or frequenting areas of 2,4,5-T use as the principal groups of individuals who may be exposed as a result of the forestry, rights-of-way, and pasture uses of 2,4,5-T. Based upon the animal test data and other information, including the Alsea study, the Agency has concluded that individuals exposed to 2,4,5-T and/or TCDD may experience adverse reproductive effects and cancer. Accordingly, the Agency concludes that it is prudent to regard individuals who may experience exposures qualitatively similar to those experienced by the Study area women as a result of the forestry, rights-of-way, and pasture uses, as individuals who may suffer adverse reproductive effects or cancer as a result of these uses of 2,4,5-T.

B. Benefits of 2,4,5-T Use During the Cancellation Proceedings

The suspended uses (forestry, rights-of-way, and pastures) comprise about 74% of the estimated 9.3 million pounds of 2,4,5-T used annually in the United States. 2,4,5-T controls a wide variety of weeds at relatively low cost.

I estimate that the economic impact of this suspension action will be small. This finding is based on several considerations. The inherent flexibility in the treatment schedules permits delays in treatment during an estimated two-year suspension period. Alternative chemical, mechanical, and manual control treatments are available and are being used. The availability of these alternatives will minimize the impacts of suspension on those acres which require treatment during the suspension period.

(1) The Forestry Use

The forestry use comprises 28% of 2,4,5-T use. 2,4,5-T's advantage is its ability to control a wide sprectrum of weeds without damaging the treated trees.

Forest managers take measures to control weeds on softwood forests on two major occasions during the approximately 50-year life of a commercial forest: (1) the preparation stage designed to clear a site of potentially damaging vegetation prior to planting, and (2) the release stage designed to free young trees (3 to 10 years old) from weed and hardwood competition in order to promote extensive growth.

I have found that the use of 2,4,5-T is not necessary for site preparation. 2,4,5-T is used only 20% of the time. Other chemicals, mechanical or manual clearing methods, or burning can be equally effective in giving newly-planted trees the opportunity to grow. The alternatives are more expensive. A two-year suspension of 2,4,5-T use for release treatments would have no serious effect because the treatments could be delayed for two years without impairing tree growth. Alternatives are generally available where weed growth makes treatment necessary. Finally, the impact on consumers of wood products is likely to be small.

(3) The Rights-of-Way Use

2,4,5-T is used to control woody and herbaceous plants on railroads, highways, electric transmission lines, and pipelines. The rights-of-way use covers 41% of total 2,4,5-T usage.

Chemical, mechanical, and manual methods of control are also used on rights-of-way acreage. Use of more than one method is common practice. The cost of 2,4,5-T is less than chemical alternatives for some methods of application, more expensive for others.

Many rights-of-way managers who have scheduled 2,4,5-T use during the suspension period are likely to postpone treatment entirely. Managers will likely use alternatives when plant growth is rapid. Even if all acres were treated with alternatives, I estimate that the additional cost of treatment on rights-of-way during suspension would not have a significant impact on users' revenues or operating costs.

(4) The Pasture Use

Weed control in pastures is now practiced on only about 1.0 million out of about 101 million acres of pastureland. There are effective chemical and/or mechanical control alternatives for all weed species in all regions. The major result of suspension on pastureland would be a delay in treatment on much of the acreage scheduled for treatment due to the inherent flexibility of decisions whether to treat. The economic impacts of a two-year suspension would be of little or no consequence.

C. Summary of Findings on Imminent Hazard

(1) The Forestry Use

In order to find an imminent hazard, I must find that the risks of use during the period likely to be required for cancellation proceedings appear to outweigh the benefits. The Alsea study, establishing a correlation between use of 2,4,5-T in forest management and miscarriages in humans, coupled with animal studies showing similar effects, indicates that there is a substantial likelihood that serious harm could result to persons with qualitatively similar exposures from the forestry use of 2,4,5-T. Aerial application, a major forest treatment method, may result in drift and increased exposure potential. This hazard to human health clearly outweighs the benefits of 2,4,5-T use during the cancellation period. The economic impacts of suspension are small because of the flexibility of treatment schedules and the availability of alternatives. Hence, I find that an imminent hazard exists for the forestry use of 2,4,5-T.

(2) The Rights-of-Way Use

For the reasons discussed below, the use patterns of the rights-of-way use create the same, or greater, potential for human exposure as the forestry use. In broad terms, considerable exposure potential exists due to the large numbers of persons living near rights-of-way and the likelihood of drift from the widespread use of aerial application. Hence, the rights-of-way use results in a hazard to human health which in my judgment outweighs the corresponding benefits. Although rights-of-way is the biggest 2,4,5-T use, a use moratorium during the cancellation proceedings would not have a significant economic impact because many rights-of-way managers are likely to postpone treatment entirely during the suspension proceedings; if they do treat, alternatives are available. Therefore, I find that an imminent hazard exists for the rights-of-way use during the cancellation proceedings.

(3) The Pasture Use

For the reasons discussed below, the application of 2,4,5-T on pastures presents exposures qualitatively similar to the forestry use, and hence the risk posed by 2,4,5-T use to human health is of concern. The exposure risk may be lower than for forests and rights-of-way. The principal application technique is spot spraying with knapsack equipment, which has less drift potential than aerial application. The benefits, however, are marginal at most. Weed control is practiced on less than 2% of pasture acreage, showing the relative unimportance of chemical or other treatments. Treatment can ordinarily be delayed or dispensed with entirely. In any case, there are effective chemical and/or mechanical control alternatives for all species in all regions of the United States. Thus, while the risks to human health from the pasture use appear to be lower than from the rights-of-way and forest uses, the economic impact of two-year suspension of the pasture use is of little or no consequence. I find that an imminent hazard exists for 2,4,5-T usage on pastures because the risks outweigh the benefits of use during the cancellation proceedings.

D. Summary of Findings on Emergency

As previously discussed, I have interpreted the statutory provision on emergency suspensions [FIFRA Section 6(c)(3)] to require a preliminary balancing of risks against benefits of use during the time for holding a suspension hearing. Hence, an emergency finding involves two issues: (1) immediate intervention is required because there is no time to hold a suspension hearing before the next period of pesticide use; and (2) the risks outweigh the benefits during the time for holding the suspension hearing. At the end of the suspension proceeding, I have discretion to affirm, modify, or reverse my suspension order.

C1) The Forestry Use

There is not enough time to hold a hearing before the next forest spraying season. Much of the year's treatment generally occurs between March and May. I am advised that in some parts of the Pacific Northwest, spraying is about to begin or has already begun. Hence, assuming 2,4,5-T use on forests poses unreasonable adverse effects, immediate action is required to stop 2,4,5-T use.

The risks posed by 2,4,5-T forestry use clearly outweigh the benefits of use during the suspension proceeding. The Alsea epidemiological study suggests that persons in the vicinity of forest spray are being exposed to the potential dangers of 2,4,5-T use. These people are about to be exposed to almost one year's dose of 2,4,5-T applications in the next two months. The emergency suspension proceeding is anticipated to run from March through June (see discussion in Section V). Hence, by the time the suspension hearing is over, it will be too late to halt much of this year's spraying.

Considering benefits, the economic consequences from a three-month delay for the completion of suspension proceedings are very small. Much of the scheduled treatment can readily be deferred for this short a period of time.

In any case, alternatives are generally available to prevent reductions in tree growth where treatment is considered essential.

Accordingly, I find that an emergency exists for the forestry uses of 2,4,5-T. Therefore, I am ordering immediate suspension of all 2,4,5-T registrations for these uses of 2,4,5-T.

(2) Rights-of-Way Use

2,4,5-T is applied on rights-of-way (railways, highways, electric transmission lines, and pipelines) during the spring growing season, which starts in March in some parts of the country. Additionally, some methods of application on rights-of-way may be year-round. Hence, there is not enough time to hold a hearing before humans are exposed to the risks to their health presented by this chemical.

The risks of 2,4,5-T use far outweigh the benefits during the time for holding a suspension hearing. The potential for human exposure from the rights-of-way use during this period is not inconsiderable even though the use season is not limited to the March-June suspension proceeding period. Large numbers of people live near rights-of-way areas, and aerial application is an important application method. On the other hand, little economic harm will result from a three-month use moratorium. Use on rights-of-way can generally be deferred for this short period of time. At any rate, alternatives are available. Chemical alternatives are cheaper than 2,4,5-T for some application methods, including aerial application.

Accordingly, I find that an emergency exists for the rights-of-way use of 2,4,5-T. Therefore, I am ordering an immediate suspension of all 2,4,5-T registrations for the use of 2,4,5-T on rights-of-way.

C 3) Pasture Use

The application of 2,4,5-T to restrict weed growth on pastures is expected to occur in March in some parts of the country and in even more areas before the anticipated completion of the suspension proceeding in June. Hence, emergency measures are required since I believe that the pasture use poses the risk of unreasonable adverse effects to human health during the suspension hearing.

The pasture use presents the risk of exposing innocent bystanders because residences are scattered throughout pastureland areas. The risk to humans from 2,4,5-T use on pastures may be lower than from use on forests and rights-of-way, because aerial application is used on forests and rights-of-way and not on pastureland. On the other hand, the benefits of use during the 3 to 4 month suspension period are minimal. Treatment can most certainly be postponed during this short period. In any case, there are effective chemical and/or mechanical control alternatives for all weed species in all regions of the country.

Accordingly, I find that an emergency exists for the pasture use of 2,4,5-T. I am therefore ordering an immediate suspension of all 2,4,5-T registrations for the use of 2,4,5-T on pastures.

IV. BASIS FOR FINDINGS CONCERNING IMMINENT HAZARD AND EMERGENCY

In Section III of this notice, I have presented a summary of my findings that an imminent hazard and emergency exist for the forestry, pasture, and rights-of-way uses of 2,4,5-T. The data, information, and analyses upon which these findings are based are detailed below.

A. Findings Relating to Adverse Effects in Test Animals

(1) Adverse Reproductive Effects in Test Animals

This section presents the test animal data upon which I relied in finding that exposure to TCDD and/or 2,4,5-T is likely to result in adverse reproductive effects in humans. Except as specified below, these data were derived from studies in which pregnant rodents were orally exposed to

TCDD and 2,4,5-T during the second trimester of gestation by daily gavage or in which primates were chronically exposed before mating. The pregnant rodents were sacrificed shortly before the scheduled birth of the offspring, and the fetuses were examined for abnormalities. The Agency has extracted key data for presentation in this report of findings. Experimental details and descriptions of the underlying data are presented in the 2,4,5-T RPAR notice and in the published literature.

(a) Exposure of Test Animals to TCDD

TCDD produces fetotoxic effects such as death and reduced fetal size; skeletal deformities such as cleft palate and clubfoot; injury to internal organs such as intestinal bleeding, intestinal lesions, and abnormal kidneys; and post-partum effects such as reduced survival. These effects appear in several different rodent strains and species, occur in all of the litters in some dose groups, and occur at doses at least as low as 0.01 ug TCDD/kg. The repeated and regular appearance of several different forms of damage to test animals of several different strains and species indicates that TCDD is a teratogenic and fetotoxic agent in mammals.

(i) Fetotoxic and Embryolethal Effects

Fetotoxic and embryolethal effects have been reported for at least three different mouse strains, two different rat strains, and one strain of subhuman primates exposed to TCDD during gestation. For example, in studies using generally low-dose regimens of TCDD, Neubert and Dillmann reported that resorption sites (resorbed or dead embryos) occurred in 54% (7/13) of the litters at 0.3 ug/kg and in 100% (3/3) of the litters at 9.0 ug/kg for NMRI mice, compared to 24-32% (23/95 and 24/65) of litters exhibiting resorptions in control animals which had not been exposed to TCDD. Sparschu et al. reported resorption of 100% (110/110) of the fetuses in Sprague-Dawley rats exposed to 8 ug TCDD/kg, compared to 20% resorption (63/309) of the fetuses from the control animals. Khera and Ruddick reported 100% (77/77) resorption of fetuses at 4 ug/kg and 36% (56/153) at exposures of 1 ug/kg in Wistar rats, compared to 2-7% (3/152 and 10/127) in the control animals. Smith et al. reported resorptions in 95% (18/19) of the litters of CF-1 mice exposed to 1.0 ug/kg, compared to 74% (25/34) in the control animals; despite the high control incidence of resorptions in this study, the increased incidence in the experimental animals was statistically significant.

In an abstract of a current study, Schantz et al. (1979) reported 57% (4/7) of pregnant monkeys aborted and one delivered a stillbirth. Two others on the 50-ppt diet failed to conceive, and two delivered normally. The eight control animals all delivered normal infants. Maternal toxicity was observed in some dose groups in some of these studies.

Similar effects have been reported at higher dose levels of TCDD. Neubert and Dillmann reported that a single dose of 45 ug/kg to NMRI mice on day 6 produced resorptions in 100% (3/3) of the viable litters, compared to resorptions in 24% (23/95) of the control litters. Courtney reported an average of 87% mortality in 6 litters of CD-1 mice orally exposed to 200 ug/kg, compared to an average mortality of 6% in 15 vehicle control litters. This investigator also reported an average of 76% mortality in 6 litters of CD-1 mice exposed subcutaneously to 200 ug TCDD, compared to 14% in the six litters of control animals. Some of these studies also describe statistically significant weight depression in the surviving embryos [e.g., Sparschu et al.).

These and other studies also report that TCDD had no measureable adverse effects at some dose levels in some strains. For example, Khera and Ruddick report no fetotoxic effects at 0.125 ug/kg in Wistar rats, and Neubert and

Dillmann report no teratogenic effects at 0.3 ug/kg in NMRI mice. Courtney and Moore reported that TCDD had no effect on fetal weight or embryonic mortality at 0.5 ug/kg in CD rats, and Sparschu et al. reported no effect at 0.03 ug/kg in Sprague-Dawley rats.

Dow Chemical Company, a 2,4,5-T registrant, has recently completed a study of the effects of TCDD on reproduction in Sprague-Dawley rats exposed to low dose-levels of this chemical for three generations. The registrant concluded that "impairment of reproduction was clearly evident among rats ingesting 0.01 or 0.1 ug TCDD/kg per day. Significant decreases were observed in fertility, litter size, gestation survival, post-natal survival, and postnatal body weight." In addition, exposure to 0.001 ug TCDD/kg per day, the lowest level tested in this study, resulted in statistically significant increases in the percentage of pups dead at birth and/or dying before the end of three weeks of life in some generations.*/

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*/ Dow Chemical Company has claimed that the results of this study are "trade secret" or "confidential." An injunction issued on April 4, 1978, in the case of Dow Chemical Co. v. Costle, Civil Action No. 76-10087, U.S. District Court for the Eastern District of Michigan (Northern Division), arguably precludes EPA from disclosing the data from this study at the present time. Although the relevant provisions of FIFRA have since been amended to allow disclosure of data such as this [see, e.g., FIFRA Sections 10(d) and 10(g)], the injunction has not yet been modified. EPA intends to promptly request the Court to modify the injunction, but until this has been done the Agency will not publicly disclose the data from the study. The summary presented in the text of this Order does not, in EPA's opinion, constitute disclosure of the allegedly "trade secret" data submitted by Dow and would not cause any harm to Dow's legitimate competitive interests. The data from the study may be made available to any party in a suspension or cancellation proceeding under an appropriate protective arrangement.

Although the experimental protocols and strains differ for the several studies cited, in each case TCDD significantly increased the incidence of resorbed embryos or stillborn animals relative to the rate observed in control animals not exposed to TCDD. The regular occurrence of embryonic death in studies by different investigators in primates and in different rodent strains indicates that exposure to TCDD during mammalian gestation may result in the death of the embryos and related maternal reproductive failure.

(ii) Skeletal Anomalies

Skeletal defects appear in six studies involving four different mouse strains. Courtney and Moore report the following incidences of cleft palate in the indicated strains exposed to 3 ug/kg TCDD: 71% (5/7) in litters of C57BL/6 mice, compared to none (0/23) in the controls; 22% (2/9) in litters of DBA/2 mice compared to none (0/23) in the controls; and 30% (3/10) for CD-1 mice, compared to none (0/9) in the controls. Neubert and Dillmann, also using 3 ug TCDD/kg, reported 29% (7/24) of the viable litters had fetuses with cleft palate for NMRI mice compared to 6% (10/160) of the control litters. Smith et al. reported cleft palate in 71% (10/14) of CF-1 mouse litters at 3 ug/kg, compared to none (0/34) in the controls.

In exposures of shorter duration, Moore et al. reported cleft palate in 86% (12/14) of C57BL/6 mouse litters exposed on days 10-13 to 3 ug/kg, compared to none (0/27) in the control litters. Neubert and Dillmann reported cleft palate in 71% (10/14) of litters of NMRI mice exposed to a single 45 ug/kg dose on day 11, compared to 6% (6/95) of litters in the controls.

Courtney and Moore reported no cleft palate in any of the litters in CD rats exposed to 0.5 ug/kg. Similarly, Khera and Ruddick, using Wistar rats, reported that the occurrence of the skeletal anomalies in the fetuses exposed to 2.0 ug/kg was comparable to the rate for the untreated animals.

(iii) Injury to Internal Organs

Exposure to TCDD produced injury to the kidneys and intestinal tracts of at least five different mouse and rat strains. Smith et al. reported 28% (4/14) of litters with kidney anomalies at 3 ug/kg in CF-1 mice, compared to none (0/34) in the controls. Moore et al. reported 100% (14/14) of litters with kidney anomalies in C57BL/6 mice exposed to 3 ug/kg on days 10-13, compared to none (0/27) in the control litters. Courtney and Moore reported kidney anomalies in 100% (10/10) of the litters of CD-1 mice at 3 ug/kg, compared to 33% (3/9) in the controls, and 67% (4/6) litters with abnormal kidneys in the CD rat at 0.5 ug/kg as compared to none (0/9) in the control litters. Sparschu et al. reported hemorrhages or lesions of the intestine of 36% (36/99) of the fetuses of Sprague-Dawley rats exposed to 0.5 ug/kg, compared to none (0/246) in the control fetuses.

(b) Exposure of Test Animals to 2,4,5-T

Cleft palate, high incidences of fetal mortality, reduced fetal weight, and other indicators of injury to the developing fetus have been reported in several studies in which test animals were exposed to 2,4,5-T contaminated with varying levels of dioxin. Some of these effects have been reported in test rodents at maternal doses as low as 10 mg/kg 2,4,5-T containing no detectable TCDD (limit of detection: 0.5 ppb).

For example, Neubert and Dillman (1972) studied the effects of 2,4,5-T contaminated with dioxin in NMRI mice. Using 2,4,5-T with 0.05 ppm TCDD, these investigators reported resorptions in 57% of the litters and cleft palate in 71% of the litters at 60 mg 2,4,5-T/kg, compared to 24-32% resporptions and 6% cleft palate in the controls.

Similarly, Courtney and Moore (1971) reported that oral exposure of CD rats to 80 mg/kg 2,4,5-T containing 0.5 ppm TCDD led to 52% fetal mortality per litter, compared to 3.4% in the controls. At this dose, kidney anomalies were observed in 50% of the litters, compared to none in the controls, but none of the fetuses had cleft palate at any dose. However, subcutaneous injection of 100 mg/kg 2,4,5-T containing 0.05 ppm TCDD led to cleft palate in 40% of the litters of CD-1 mice, compared to none in the controls.

The Dow Chemical Company, a 2,4,5-T registrant, has recently completed a study (Smith et al. 1978) of the effects of 2,4,5-T (containing less than 0.5 ppb TCDD) on reproduction in Sprague-Dawley rats exposed to 2,4,5-T for three generations. The registrant reports that exposure of these animals to 10 and/or 30 mg 2,4,5-T/kg per day resulted in statistically significant increases in the frequency of stillborn rat pups, and/or decreased survival of the pups that were born alive.*/

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*/ Dow Chemical Co. has also requested confidentiality for the results of this study. The discussion in the footnote in Section IV.A.(1)(a)(i) also applies to these data.

(c) Other Effects in Test Animals

Recently, Highman et al. showed that impaired fetal kidney development followed maternal treatment with 120 mg/kg of 2,4,5-T on days 6-14 of gestation. The impaired development was associated with a significant reduction in cellular alkaline phosphatase. TCDD has been found to induce delta aminolevulenic acid synthetase (ALA) in chick embryos with as little as 1.5 ng/egg, and Goldstein et al. found a two-fold induction of ALA in C57BL/6 mice as a significant 2,000-fold accumulation of porphyrins in the liver occurred when compared to controls after treatment with 25 ug/kg of TCDD. Abnormal porphyrin synthesis occurred in female rats when treated in a chronic study at 0.01 ug TCDD/kg per day (Kociba et al. 1977). Alkaline phosphatase and gamma glutamyl transferase levels in female rats on 0.1 ug/kg significantly increased when compared to controls.

(2) Oncogenic Effects in Test Animals

(a) Exposure of Test Animals to TCDD

The Carcinogen Assessment Group (CAG) has concluded that TCDD induces carcinogenic responses in mice and rats at exceedingly low dose levels and that these effects, together with data showing that TCDD is mutagenic, constitute substantial evidence that TCDD is likely to be a human carcinogen.

Dow Chemical Company, a 2,4,5-T registrant, studied the effects of TCDD on male and female Sprague-Dawley rats exposed to 0.022, 0.220, or 2.2 ppb TCDD. CAG agrees with the registrant's conclusion that there is a statistically significant increase in the incidence of heapatocellular carcinoma in female rats exposed to 2.2 ppb TCDD. In another study using Sprague-Dawley rats, Van Miller reported that 1 ppb and 5 ppb TCDD produced a carcinogenic response in the livers of male Sprague-Dawley rats. These observations tend to confirm the registrant's observations that TCDD produces an oncogenic response in the livers of male Sprague-Dawley rats.*/ Further, a preliminary report of a not-yet-completed National Cancer Institute study tends to confirm these observations of a carcinogenic response in rats. A contractor for the National Cancer Institute has reported that TCDD is carcinogenic in the rats and mice used in that study.

CAG also emphasized that, at low levels, TCDD is a potent inducer of arylhydrocarbon hydroxylase, an enzyme system that contains an enzyme that is known to mediate the formation of epoxides, compounds which are potentially active carcinogenic metabolites.

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*/ The CAG and an EPA audit found that this study had major shortcomings in design and conduct that limited the reliability of the data developed at dose levels lower than 1 ppb.

CAG also reported that TCDD is mutagenic in the Ames test without the metabolic activation system. Its mutagenic activity is exhibited by frameshift mutations caused by intercalation between base-pairs of DNA.

(b) Exposure of Test Animals to 2,4,5-T

On the basis of its review of 10 chronic toxicity studies, eight using mice and two using rats, CAG has concluded that there is no significant evidence in the completed studies that 2,4,5-T is carcinogenic in these species. Specifically, CAG reported that exposure to 3, 10, or 30 mg 2,4,5-T/kg (TCDD not detectable at detection limits ranging from 0.12 to 0.33 ppb) does not have carcinogenic effects in Sprague-Dawley rats. Preliminary data from a rat study in progress are also negative. Nonetheless, these findings do not negate the cancer-causing potential of 2,4,5-T as commercially produced since it contains the TCDD contaminant.

CAG's review of the design and conduct of other studies disclosed that testing in mice is inadequate because the maximum tolerated dose may not have been used in some of the studies in which mice showed no carcinogenic response, and because there were significant defects in the design and execution of a study for which the authors initially reported a statistically significant increase in tumors in female mice.

B. Findings Relating to Risk to Humans

(1) Study of Miscarriages in Alsea, Oregon

(a) General Discussion

In response to the 2,4,5-T RPAR notice, a group of eight women informed the Agency that they lived within 12 miles of Alsea, Oregon, where 2,4,5-T is used in forest management and that they had experienced a total of 13 miscarriages between 1972 to 1977. In their letter, the women presented information showing that most of their miscarriages occurred eight to ten weeks after conception and followed by four or six weeks the date of the spring application of 2,4,5-T in the forest areas in which these women reside. The women indicated their belief that this information suggested that the unusually high number of miscarriages in their group was related to the use of 2,4,5-T.

The effects which these women reported were comparable to the embryolethal and fetotoxic effects observed in test animals that have been exposed to 2,4,5-T and/or TCDD. Moreover, because embryos are particularly susceptible to the harmful or lethal effects of fetotoxic or teratogenic agents during the early stages of pregnancy, the occurrence of these miscarriages within approximately two months of the use of 2,4,5-T in the Alsea area suggested a possible relationship between the use of the pesticide and the miscarriages reported for this group of women. For these reasons, the Agency began an epidemiological study to determine if the occurrence of the spontaneous abortions in the entire Alsea area (parts of three counties comprising about 1,600 square miles) bore any relation to the use of 2,4,5-T in the area. To answer this question, the Agency gathered information and data from hospitals on the occurrence of spontaneous abortions in the Alsea Study area and compared these data to comparable data from a rural area where there was little or no known use of 2,4,5-T or other dioxin-contaminated phenoxy herbicides (Control area). Data on spontaneous abortions from an Urban area near Alsea were also reviewed for the study.

The Agency's preliminary analysis of the data generated through this study indicates that:

(1) The spontaneous abortion index*/ (hospitalized miscarriages per 1,000 births) for the Alsea Study area where 2,4,5-T was used was significantly greater than the index for the Urban and Control areas where there was little or no known use of 2,4,5-T;

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*/ The investigators determined the spontaneous abortion index by relating the number of hospitalized spontaneous abortions to the number of live births, corresponding to month of conception. The ratio derived in this way is expressed as abortions/1,000 births, related to month of conception, and permits comparison between areas of different total population size. The index is based on a five-month moving average for births to correspond with monthly miscarriages for terms up to 20 weeks (about five months).

(2) There was a dramatic increase in the spontaneous abortion index for the Study area relative to the Urban and Control areas in the months of June and July; this increase followed, by approximately two months, a period in March and April when 2,4,5-T was used to control vegetation in the forested Study area; and

(3) Statistical anlyses of these data indicate that there was a significant correlation between the amounts of 2,4,5-T used in the Study area during the spraying season and the subsequent increase in the spontaneous abortion index in the Study area.

In conclusion, the Agency's systematic survey of the occurrence of spontaneous abortions in an area of 2,4,5-T use indicates that there was an unusually high number of spontaneous abortions in the area, and that the incidence of spontaneous abortions may reasonably be related to the use of 2,4,5-T in the area. The data further indicate that the miscarriage experiences which the eight Alsea women reported to the Agency were representative of the experiences of the larger population of women living in the Study area. The data and information which provide the basis for these conclusions are summarized below.

(b) Results and Analysis

Comparison of the spontaneous abortion indices for the Study, Urban, and Control areas for the period from

1972 through 1977 shows that women living in the Study area where 2,4,5-T is used were more likely to experience spontaneous abortions than women living in either the Urban or Control areas (Table 1). The six-year spontaneous abortion index averaged 80.8 for the Study area, compared to averages of 43.8 and 65.4 for the Urban and Control areas, respectively.

In addition to this general elevation in the Study area spontaneous abortion index, there was a striking increase in the Study area index for the months of June and July. During June, the index in the Study area was 130.4, compared to 44.9 and 46.0 in the Urban and Control areas, respectively. For July, the indices were 105.4 for the Study area, compared to 14.6 and 55.3 for the Urban and Control areas, respectively. These data are presented graphically in Figure A.

The increased spontaneous abortion indices in the Study area during June and July are particularly significant when viewed in terms of data on the use of 2,4,5-T in the

Study area.*/ Spraying records for the Alsea area for the study period indicate that 2,4,5-T use occurs primarily between March 1 and April 30; substantially lower amounts of the pesticide are used during May and still lower amounts are used during July and August (Figure B). Examination of this information on the use of 2,4,5-T in light of data on the increased incidence of spontaneous abortions reveals

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*/ The preliminary report inadvertently included 3,530 pounds of silvex as 2,4,5-T in the estimates of usage in the Study area. Conceptually, this flaw is not significant: 1) since its effect would merely modify slightly the very significant correlation coefficient between herbicide use and miscarriages; 2) the nature of the relationship between time of application and the miscarriages is expected to remain unchanged; and silvex contains TCDD and could be expected to result in the same effect.

Nonetheless, the Agency immediately had the analysis rerun to determine whether specific change in numerical estimates result.

Corrected 2,4,5-T use remained significantly correlated with miscarriages occurring 2-3 months later ($r=.72$; $p<.01$). Combined silvex and 2,4,5-T spray data were also correlated with miscarriages since both compounds could be hypothesized to cause the observed effect due to a common TCDD contaminant. This analysis also showed strong correlation between use of herbicides containing TCDD and miscarriages as would be expected on the basis of animal studies ($r=.69$; $p<.02$).

The relative insensitivity of the correlation to changes in quantity further demonstrates the inherent strength of the relationship between the basic use pattern and miscarriages occurring approximately 2 months later.

Table 1. Monthly Spontaneous Abortion Index for the Study, Urban, and Control Areas (Oregon, 1972-1977)

Month	Study Area	Urban Area	Control Area	Average
January	48.1	73.9	82.0	68.0
February	82.2	49.3	28.1	53.2
March	93.8	43.9	48.1	61.9
April	61.9	47.0	97.5	68.8
May	89.9	50.8	63.2	68.0
June	130.4	44.9	46.0	73.8
July	105.4	14.6	55.3	58.4
August	88.1	31.8	79.8	66.6
September	46.0	49.6	85.3	60.3
October	76.2	54.8	50.5	60.5
November	76.7	19.6	54.3	50.2
December	70.3	45.6	94.5	70.1
Average	80.8	43.8	65.4	63.3

Figure A. Plot of Monthly Spontaneous Abortion Index for the Study, Urban, and Control Areas

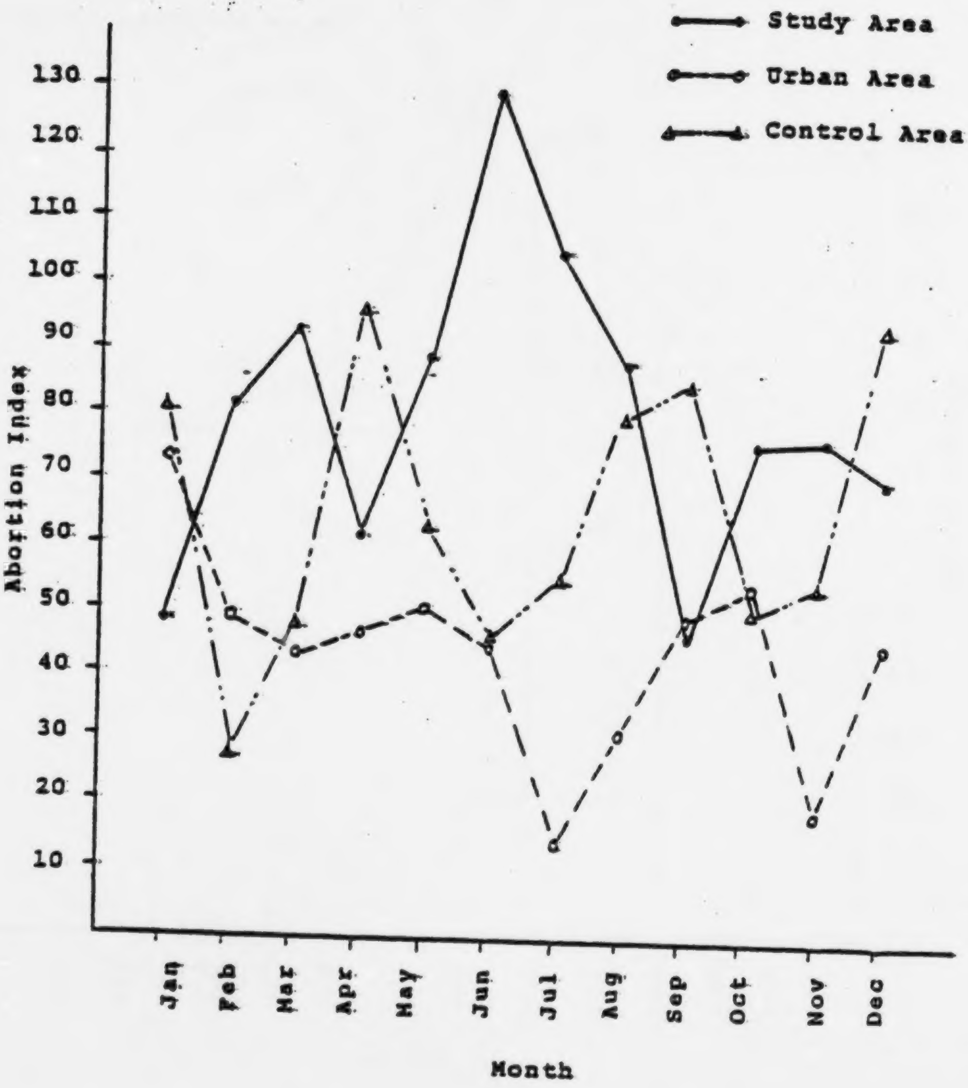
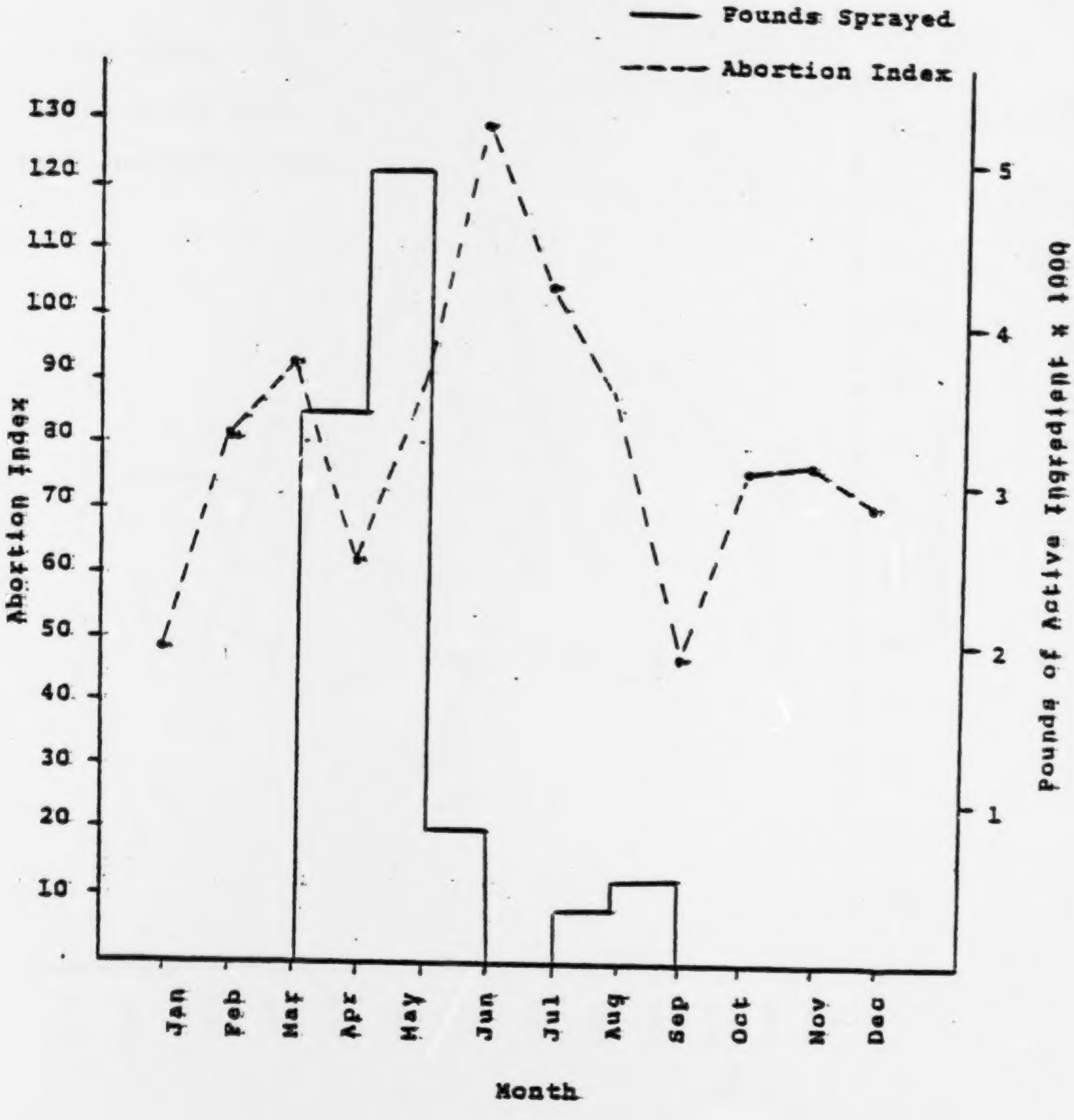


Figure B. Pounds of 2,4,5-T Sprayed in Alsea Basin Accumulated by Respective Month, 1972 through 1977, Compared with Abortion Index for the Same Period



that this increase occurs approximately two months after the period of annual application of 2,4,5-T in the Alsea area.

More refined analysis of these data on total abortions and total 2,4,5-T use by month during the period from 1972 to 1977 indicates that there was a statistically significant correlation between the abortion index in the Study area and the amount of 2,4,5-T used there. That is, when the increased spontaneous abortion index was compared to the amount of 2,4,5-T used each month in the areas where the women resided, the peak in the abortion index followed the peak in the spray pattern by approximately two months. This two-month lag time corresponds to the time predicted on the basis of the initial reports from the eight Alsea women. Because this correlation is statistically significant ($p<0.01$), there is strong reason to suspect that the spontaneous abortion increase was related to the use of 2,4,5-T.

In view of the laboratory data establishing that 2,4,5-T and its contaminant TCDD have embryolethal effects in test animals and the susceptibility of the young embryo to fetotoxic and teratogenic agents, the increased spontaneous abortion index in an area of 2,4,5-T use may reasonably be interpreted to be a consequence of the exposure of women residents of the area to the 2,4,5-T used for forest management.[*]

(2) Seveso (Italy) and Vietnam

(a) Seveso, Italy

On July 10, 1976, an accident at the ICMESA chemical plant in the Seveso region of Italy released 2 to 10 pounds of TCDD over a wide area. Hundreds of animals died, many area residents reported skin disorders, and an area of 110 hectares was evacuated. The most pertinent reports on this incident are provided by Reggiani (1977), Tuchman-Duplessis (1977), and Whiteside (1977; 1978).

There is an apparent consensus that the reproductive epidemiology of Seveso, as presented, does not provide firm evidence of increased risk of spontaneous abortions or congenital malformations following the explosion. The

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[*] The Alsea experience may not be an isolated incident. Reports of people adversely affected by exposure to phenoxy herbicides and/or TCDD have frequently appeared in medical and scientific journals. Recent summaries appear in IARC, NRCC, and U.S. Air Force documents on phenoxy herbicides and dioxins. Further, as a result of the 2,4,5-T RPAR, the Agency recently received numerous accounts of human health effects attributed to phenoxy herbicides and/or TCDD. These have been summarized in a document included in the record. The cumulative effect of these reported incidents suggests that people who live and/or work in areas of 2,4,5-T use may experience adverse health effects.

Agency does not believe, however, that those investigations provide sufficient evidence of the absence of increased teratogenic risk in humans, either for dioxin in general or among the women of Seveso in particular. There are three reasons for this conclusion: (1) deficiencies in the available data; (2) methodologic deficiencies in the treatment and interpretation of the data which are available; and (3) suggestive indications in the available data that there may actually have been an increase in teratogenic risk in the area after the incident.

Major points which illustrate deficiencies in the available data include: reproductive data in the area "either do not exist or are deliberately underreported" (Reggiani 1977); baseline rates for spontaneous abortions and congenital malformations in the area prior to the incident are not available; less than complete cooperation was obtained from local physcians and less than complete registration of pregnant women was attained (623 pregnant women were registered, but 2,513 deliveries were recorded in the area for July 1976 to May 1977; registration was thus about 25%); while 34 women obtained therapeutic abortions in the area, it is estimated that more than 2 times that number obtained them legally or illegally elsewhere (Whiteside estimates the number to be 4 times as many); and the conventional pitfalls of reproductive epidemiology could not be avoided (e.g., dependence on hospitalized spontaneous abortions for numerators and hospitalized births for denominators and different gestational cohorts for spontaneous abortions and births occurring in the same calendar period).

Major points which illustrate methodologic deficiencies in the treatment and interpretation of the available data include: estimates of the total amount of dioxin released ranged from 650 g (Reggiani 1977) to 11 kg (Whiteside), to 130 kg (Nature 11/28/76); estimates of exposure per person varied from 29 ug/m^2 (Tuchman-Duplessis) to 5,620 ug/m^2 (Reggiani 1977); exposure was characterized by geographic zones, but reproductive data were gathered by geographic districts raising questions whether the zones were contiguous with the districts; spontaneous abortion rates were grouped in 6-month intervals, but congenital malformation rates for 1976 were grouped in 12-month intervals which could have masked an effect expected to be relatively acute or with a 2-3 month lag period; and the rates listed as "totals" for the two groups of districts in Table 13 (in Reggiani 1977) appear to be averages of the district rates and as such are invalid and cannot be interpreted; the lack of chromosomal abnormalities in the products of therapeutic abortions is overemphasized since dioxin could conceivably produce a teratogenic effect without producing a concomitant mutagenic effects and the wide interspecies variation seen in lethality studies should not automatically be applied to teratogenic effects because it is known that very low doses are teratogenic in the rat (e.g., 0.01 ug/kg) and dioxin doses which caused teratogenic effects in rhesus monkeys were apparently as low as 2.5, 50, and 500 nanograms/kg.

Suggestive indications of a possible teratogenic effect in humans, from the available data, includes the congenital malformation rate increased by 570% (about 7-fold) between 1976 and the first five months of 1977 (Table 14, 0.13 to 0.87 per 100 live births) (in Reggiani 1977). The birth rate dropped "sharply" following the explosion and cows aborted and produced malformed offspring following the explosion. (Whiteside). A local doctor noted a "marked increase" in convulsions among infants. (convulsions could be delayed effects of neurotoxicity in utero). [Whiteside]).

(b) Vietnam

A large amount of TCDD- contaminated herbicides were used in Vietnam during 1962-1971. Possible health effects have been reported upon retrospectively by groups entering Vietnam. Tung et al. charged that 2,4,5-T was responsible for much of the Down's Syndrome seen in

[South] Vietnam. Crummer was quoted by Honoroff as having observed high incidences of children with Down's Syndrome. Tung et al. also noted a very significant increase in the Hanoi hospitals in hepatic carcinomas in the period 1962–1968 [1790/7911 cancer cases (10%), compared to 159/5492 (2.9%) for the period 1955–1961].

It should be remembered that most of the accidents reported here were retrospective accounts. In the cases of Seveso and Vietnam, reporting was (and still is) at best piecemeal. The exposed populations contained numbers of highly mobile persons who could not be accounted for adequately.

(3) Exposure Analysis

(a) General Considerations

There are two components to any pesticide-related risk: (1) the toxicological properties of a chemical, and (2) exposure to the chemical. The risk assessment is a summation of the conclusions in each of these areas. A highly toxic chemical may pose high risk even if exposure is low; conversely, a compound of low to moderate toxicity may pose high risks if exposure is high.

Estimating probable exposure is difficult for a number of reasons. While it would be inappropriate to attempt a definitive discussion of these problems here, it is useful to note a few examples. First, empirical data on exposure is less available than is toxicology data. Second, there are a number of exposure pathways which require consideration (e.g., inhalation, dermal absorption, ingestion of food residues, and ingestion of water residues). Third, the inherent complexities of the dynamics of a chemical's movement through the environment create formidable obstacles to describing any given exposure pathway. For example, the chemical may behave differently in various media depending upon a number of environmental factors which can vary at any one application site. Thus, even when some empirical data on a given route of exposure is available, there are often uncertainties concerning the applicability of the data to situations involving conditions which vary from those which obtained at the study site.

The inherent difficulties of exposure assessment always create a troublesome problem for decision makers. These problems are of great concern in situations involving chemicals which appear to pose risks even at very low levels of exposure. As discussed above, the TCDD contaminant in 2,4,5-T is clearly such a chemical. For example, TCDD is carcinogenic in rats at doses as low as 1 ppb and fetotoxic in mice at doses as low as 0.01 ug/kg/day.

Moreover, the complexities of exposure assessment are also amplified in situations involving persistent chemicals. This is because the length of time a chemical persists in the environment can increase the opportunities for movement of the chemical and confound attempts to eliminate pathways as pathways of concern. Time increases the possibilities of variation in enviromental factors affecting chemical mobility.

The environmental persistence of 2,4,5-T is relatively short due to physical, chemical, and biological degradation processes. On the other hand, the contaminant TCDD has a much longer persistence in soil and is known to bioaccumulate in fish (Matsumura and Benezet, 1973; Kearney et al., 1973).

Generally, exposure assessments involve attempts at modeling the likely exposure potential through several pathways which are identified as pathways of principal concern. The exposure assessment typically will involve attempts to describe the movement of the chemical from the site of application to persons potentially at risk, using such empirical data as are available on the presence of the chemical at various intermediate points in the critical path. Conservative assumptions based upon such things as knowledge about the behavior of similar chemicals, typical environmental conditions affecting the use site, and the like, are used to bridge inevitable gaps in the empirical data. The objective, however, is a simple one: to obtain a qualitative and (if possible) quantitative description of the likelihood that a given chemical will move from where it is applied to a given group of potentially exposed individuals.

Since 2,4,5-T first surfaced as a subject of regulatory concern, determining potential exposure has been the critical issue on the risk side of the regulatory equation. Uncertainties about exposure resulted in suspension of regulatory action in 1974, and the launching of an ambitious project to generate exposure data (the "Dioxin Implementation Plan" or "DIP"). Primarily because of great difficulties encountered in developing analytical methodologies with sufficient sensitivity to measure the extremely low levels of TCDD which are of biological concern, the progress of the DIP has been disappointing. To date, it has yielded only fragmentary information.

In my judgment, the information which has recently come to my attention as a result of the Alsea study constitutes a dramatic and troubling new point of departure for analysis of TCDD exposure concerns. As indicated above, these data show a striking relationship between 2,4,5-T use and increased incidences of spontaneous abortions among women residing in the use area. As further developed above, this effect is an effect which one would have predicted as a likely outcome of human exposure, based upon a body of animal data of almost unprecedented conclusiveness. The Alsea study, to be sure, contained no data showing actual exposure. However, concern for the health of humans who may be exposed to 2,4,5-T and its contaminant, TCDD, is heightened because scientists have not demonstrated that there is a level of exposure that has no adverse effects in humans.*/ Thus, in the face of the highly significant relationship which the study showed, and the animal data, I conclude it is reasonable and in the public interest to assume that the women in the Alsea study were exposed to TCDD.**/

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*/ A committe of the National Research Council of Canada recently agreed with the authors of the World Health Organization's monograph on TCDD that "for TCDD a no-effect level for man could not be established" (NRCC 1978).

**/ I have found it prudent to suspend because data from the Alsea Epidemiological Study indicates that women experiencing adverse reproductive effects may have been exposed to 2,4,5-T. Information of this kind concerning a chemical's effects on human populations is rarely available. Before the Alsea Study was completed, Agency scientists developed preliminary exposure analyses for 2,4,5-T based on use information, assumptions, and modeling. Since I have information of adverse human effects correlating with the use of 2,4,5-T, I have chosen to rely on this correlation as a basis for regulatory action, rather than on exposure analyses based exclusively on use information and modeling.

Moreover, I also conclude that it is prudent to assume that individuals who frequent or live in areas where 2,4,5-T is used may be exposed to TCDD in ways and under conditions which may cause these individuals to be exposed in ways qualitatively similar to those experienced by the Study area women.

As developed below, I find that 2,4,5-T use patterns likely to cause exposure opportunities similar to the exposure experienced by the Study area women are the forestry, rights-of-way, and pasture uses of 2,4,5-T. The Agency has identified pesticide applicators and persons involved in pesticide application support activities, and persons living in or frequenting areas of 2,4,5-T use as the principal groups of individuals who may be exposed as a result of the forestry, rights-of-way, and pasture uses of 2,4,5-T.

(b) The Alsea Study Area

(i) Description of Area

The Alsea Study Area comprises approximately 1,600 square miles of Oregon's forested Coastal Range centered around the "Alsea basin," an area of approximately 400 square miles. It is bounded on the west by approximately 70 miles of the Pacific Coast and extends inland for distances ranging from 10 to 35 miles. The Study area includes all but the northern and southern reaches of the Suislaw National Forest. Numerous commercially owned and Bureau of Land Management forested acreages are interspersed throughout this region. Mountain elevations of approximately 1,000 feet are not uncommon; peak elevation is slightly more than 4,000 feet. The principal rivers are the Siletz, Alsa, Yaquina and the Suislaw. Eastern fringes of the area drain eastward into the Willamette Valley. Maximum runoff is reached generally during the winter months as the result of storms off the Pacific occurring usually as rain.

The Study area is predominantly rural. The four largest towns have a total population of 14,450. All other towns/villages have populations of less than 1,700. Alsea has a population of 400 (1970 census). In addition, many residences are scattered througout the forest areas. All of the nine women who were identified in the first phase of the investigation resided, at the time of pregnancy, in rural residences located within 12 miles of Alsea.

(ii) Use Pattern

2,4,5-T is applied to the forests in the Alsea area almost exclusively by helicopter for control of undesirable vegetation such as red alder, vine maple, salmonberry, and thimbleberry. In general, the compound is used in the spring (March, April, or May) with a second application made, if needed, in middle to late summer (July or August). Over the six-year study period, 10,000 pounds of 2,4,5-T was distributed over a total area of approximately 7,000 acres. The usual practice was to treat any particular site approximately once every five years. However, contiguous stands could be treated in succeeding years. The spray program spans only a few days' time, with the duration depending on the number of acres to be treated and the weather conditions.

To avoid contamination of water sources prior to 1978, the general application policy was to avoid spraying near homes and to provide for a single swath of 30 to 60 feet on each side of any major stream. In September 1978, the Oregon Forest Practices Act created guidelines which prohibited spraying within 500 feet of an inhabited residence or within 200 feet on either side of streams with fish and/or ones that are used for domestic water supplies. However, drift and runoff could contaminate surface waters.

(iii) Population Exposed to the Herbicide

Population of the Alsea Region is clustered in several small towns; there are also isolated homes and farmsteads in the forest area. Groups which may be traversing the forests of the Alsea Region include residents, workers engaged in forest management, incidental travelers, hikers, students, surveyors, and delivery persons.

(iv) Modes of Exposure

The major method of dispensing 2,4,5-T in the Alsea Forest Region is by helicopters. Although the Oregon Forest Practices Act prohibits spraying near homes or streams, there appears a likelihood that residents and travelers of the Alsea Region might be directly exposed to 2,4,5-T during periods of application as a result of drift. Drift from a helicopter flying over a forest canopy can produce drift of the herbicide spray at significant distances from the path of the aircraft. Residents or travelers in the path of the spray might be doused with the pesticide spray.

Exposure to the population from drift and direct contact is by the dermal (exposed skin) and inhalation routes. Resident populations may also incur exposure to 2,4,5-T and TCDD subsequent to application. Waterborne residues are a possible route of exposure; other possible exposure routes include fish, wildlife, and other foods produced or found in the area. The fact that TCDD is somewhat persistent and bioaccumulative may enhance exposure possibilities. Furthermore, pesticide mixers, loaders, applicators, and other workers may be exposed to the pesticide.

(c) Comparison Between Presumed Exposure in The Alsea Study Area and Possible Exposure in Other Use Situations

The Alsea Study shows a significant correlation between the use of 2,4,5-T in the Alsea area and increased incidence of spontaneous abortions within approximately two months after application. The Agency believes that it is prudent to assume that the women studied were exposed to 2,4,5-T. While the Agency cannot determine the actual routes of exposure, information about how 2,4,5-T is applied, population densities, and proximity of Study area residents to spray areas provides a basis for making assumptions about possible chances for exposure.

That 2,4,5-T was applied by helicopter rather than by ground application methods in Alsea, enhanced the potential for exposure to 2,4,5-T from drift. Aerial application is a principal method for applying 2,4,5-T. A substantial amount of the 2,4,5-T applied in forests and on rights-of-way is applied aerially. In contrast, in pastures, application of 2,4,5-T usually is by spot treatment with knapsack spraying equipment. This method, causing less spray distribution than aerial application, lessens potential exposure from drift.

Alsea inhabitants live in towns and residences scattered throughout forests in which 2,4,5-T was applied. Effects occurred even though application near residences and streams was prohibited. The Study area women who experienced spontaneous abortions were residents of the area. Their exposure to 2,4,5-T may have occurred either while they were at home or while they were in nearby forest areas. Bystanders, workers engaged in forest management, people visiting the forests for recreational purposes, and others would have exposure potential similar to the exposure potential of the Study area women away from their homes. Because TCDD persists in the environment, such non-residents may have been exposed to 2,4,5-T and TCDD during or for some unknown length of time after application had occurred.

The Study area women may have been exposed to 2,4,5-T or TCDD through ingestion of drinking water, fish, and wildlife. Residents are more likely to be exposed through this route than infrequent visitors to the spray area. Frequent visitors or workers in the area would have exposure potential similar to that of residents. All other forest areas in which 2,4,5-T is used are most obviously similar to the Study area.*/

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*/ Commercial forests are defined as those lands not withdrawn for non-timber purposes which are capable of growing 20 cubic feet of wood per year of desirable species.

The use of 2,4,5-T to maintain rights-of-way involves exposure potential similar to the exposure potential of the Study area women. residents of the application area and workers and visitors who frequent the area may be exposed.

The Agency estimates that a considerable number of people may be exposed to 2,4,5-T and TCDD as a result of the use of 2,4,5-T in non-urban areas to maintain rights-of-way. Rights-of-way uses include highways, railway lines, electric power lines, and pipelines. A principal method of applying 2,4,5-T is by aircraft, which was the method of application in the Alsea, Oregon area.

The population that is most likely to be exposed are people who live in the path of the spray or in the area of drift.*/ A large potential exposure group would be comprised of people living along railroad tracks and along highways. Other groups that may be exposed are those that live in forests or plains along power lines and pipelines. The residents may be exposed to TCDD through the diet for longer periods of time due to low levels of TCDD contamination in water and food. An additional potentially exposed group are people working in, or traveling through, the treated area.

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*/ Factors which affect drift include wind direction and velocity, turbulence, relative humidity and air temperature, atmospheric stability, pesticide formulation, application equipment, and spray volume. For purposes of this analysis, the Agency conservatively estimated possible pesticide drift at 1/2 mile. The Agency notes, however, that pesticides could drift farther depending on the variables listed above. Some pesticide drift has been reported as far as 22 miles from target (EPA DRAFT: "Report to Congress/Study - ULV," p. 95). In addition, this same draft report estimates that percent of pesticide drift over 1,000 feet from the target variously ranges from a low of 10% to a high of 90%.

Exposure from the use of 2,4,5-T in pastures is likely to be lower than the Study area.[**/] Pastures are likely to be near farmhouses and small towns. The populations which may be exposed to 2,4,5-T include farm families, other rural residents, and workers in rural occupations. The predominant method of application for controlling brush in pastures is spot treatment with knapsack spraying equipment. The distribution of 2,4,5-T from this technique is lower than that from forestry and rights-of-way use, because this technique produces only short-range drift. Indirect exposure due to residues in food is possible.

Generally, persons involved in applying pesticides have greater exposure to the chemicals than do residents of

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[**/] Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

the area in which the pesticides are used. There is no reason to believe that this would not be true of 2,4,5-T. Therefore, the Agency is concerned about potential exposure to pilots, ground spray crews, mixers and loaders, and flaggers, all of whom are exposed to 2,4,5-T in the application process.[*]

For aerial application, the ground crew, including mixers and loaders of the aircraft, is the group with the highest potential for exposure by both dermal and inhalation routes, because they handle the concentrated formulations (up to 41% of 2,4,5-T acid by weight). The flaggers on the ground are exposed mainly by drift of the diluted spray deposited on their exposed skin, and to a lesser degree by inhalation. The pilots are expected to be exposed to smaller amounts of 2,4,5-T by dermal and inhalation routes because they sit in the enclosed cabin of the helicopter while applying the diluted herbicide spray. For the ground application techniques, the applicators and mixers are the workers running exposure risk. Inhalation exposure may be more significant when fine mist sprayers (for example, foliar treatment) are used in contrast to stump treatment spraying with a coarse spray. The reason for this is that smaller spray droplets are more readily absorbed through the lungs.

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[*] In response to the 2,4,5-T RPAR, the American Paper Institute and the National Forest Products Association recently submitted a detailed study of aplicator exposure to 2,4,5-T during both areial and ground applications (2,4,5-T RPAR submission #1023H - 30000/26). The results of this study indicate that workers who handled the pesticide concentrate had the highest exposure, followed by knapsack sprayer applicators, mist blower drivers, helicopter pilots, supervisors, and flagmen.

C. Determination of Benefits

The Agency has evaluated the potential economic impacts of suspending the forestry, pasture, and rights-of-way uses of 2,4,5-T during 1979 and 1980.*/ The consideration of economic impacts stemming from a suspension is limited to a two-year period because the maximum projected length of a cancellation proceeding would be two years. A suspension order remains in effect only during a cancellation proceeding. Thus, only the impacts which would arise during this period would be at issue in a suspension. Any impacts which would be caused by a suspension, but which would be felt after this period, are also considered.**/

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*/ The emergency suspension order will take effect immediately upon issuance of this Notice and remain in effect during any subsequent emergency suspension hearings. At the conclusion of the hearings, a decision will be made whether to continue or remove the suspension order during the ensuing cancellation proceedings. Ecomonic impacts are therefore separately evaluated for the 3 1/2 month period allocated for an emergency suspension proceeding as well as for the two years which may be required for a cancellation proceeding.

**/ The Agency's analysis is based on information from a number of sources including RPAR rebuttal comments received by the Agency from registrants, users and other parties during the RPAR process; and the USDA-States-EPA 2,4,5-T RPAR Assessment Report (February 15, 1979) as well as other relevant data. Although the 2,4,5-T Report attributes a role to EPA, the final report has neither been completely reviewed nor approved by EPA. Therefore, although the Agency has relied on some portions of the report, it cannot and does not wish to adopt all portions of the report as reflecting the Agency position on matters discussed therein.

2,4,5-T is registered for control of woody and herbaceous plants on rights-of-way, forestry, range, pasture, and rice. The suspended uses (rights-of-way, forestry, and pasture) comprise about 74% of the estimated 9.3 million pounds of 2,4,5-T active ingredient used annually in the U.S. Rights-of-way usage (3.8 million pounds) is the single largest use, comprising an estimated 41% of total annual usage; forestry (2.6 million pounds) and pasture usage (500,000 pounds) account for about 28 and 5%, respectively, of annual 2,4,5-T usage.

Economic impacts of suspending forestry, pasture, and rights-of-way usage of 2,4,5-T during 1979 and 1980 were evaluated assuming all registered alternatives are available, except silvex which is also subject to suspension. The analysis often provides qualitative estimates of impacts due to a lack of data to support precise quantitative estimates.

Economic impacts during 1979 and 1980 would depend upon the treatment options actually selected by users. For many, use of alternatives to 2,4,5-T during 1979 and 1980 would be optional (i.e., could be delayed to a later year). Other users might choose to use alternatives immediately. It is not possible to predict with precision which option may be selected by the many potential users of

2,4,5-T during the suspension period.

The Agency's analysis indicates that the suspension of 2,4,5-T (and silvex) for forestry, rights-of-way, and pasture uses during 1979/80 would not signficantly affect U.S. production or prices of major commodities and services from these sectors. Impacts on productivity and costs during the two years would generally be regional in nature but insignificant on the national level. Industry impacts would be nominal within the context of year-to-year variations in economic activity due to interaction of normal supply and demand forces, as affected by weather, general monetary and fiscal policies, international economic developments, etc.

Economic impacts during the 3 1/2 month emergency suspension proceeding would negligible. The only noteworthy impact would involve the forestry use in which spring applications predominate in the Northwest. Even then, the impacts are nominal during the 3 1/2 month suspension proceeding.

The minimal nature of the overall economic impacts follows from: (a) the inherent flexibility of treatment schedules, permitting delays in treatment to ameliorate negative economic impacts of suspension; (b) the existence of chemical, mechanical, or manual alternatives (or combinations) which are currently being used on these sites, even though they are not generally as cost-effective as 2,4,5-T; and (c) the 2,4,5-T usage which normally would have occurred on the suspended sites represents a small fraction of the overall industry acreage (e.g., 0.2 percent of forestry acreage in the U.S.); concentrated acreages needing treatment with alternatives during the suspension period would occur only at the regional and local level.

Each of the suspended uses is examined in detail in the following discussion.

(1) Forestry Use

There are about 500,000,000 acres of commercial forests[*/] in the U.S. of which 1.16 million acres (0.23%) are treated annually with 2,4,5-T. This herbicide can be used at either or both of two stages in the production[**/] of conifers (softwoods): (1) preparing sites for reforestation and (2) releasing young trees from hardwood competition. Each operation is undertaken once in the 50 year cycle of a softwood stand. 2,4,5-T as well as other chemical and non-chemical control methods may be used individually or in combination for site preparation and release.

Use of 2,4,5-T for site preparation is not critical although it is cost effective. Several other chemical as well as non-chemical methods are also effective for site preparation. Picloram and 2,4-D, sometimes combined, are the most effective substitute chemicals. 2,4-D costs less than 2,4,5-T but controls a more limited spectrum of weeds.

Because the release (weeding) operation is conducted after the seedling trees are in place, a selective herbicide which will not harm the seedlings is preferred. This is particularly true for pine; only 2,4,5-T provides control of the wide variety of competing hardwoods without damaging the sensitive seedling pine. This often critical operation is most effective when performed two to ten years after establishment of the stand. If competing hardwoods are not suppressed, the seedlings may be overtopped, and stand growth and density may be decreased. The benefits of weed control for release and site preparation of conifer crops are increased yields at harvest time. For stands receiving no weed control for site preparation or release, annual growth can be substantially reduced on the most productive sites.

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*/ Commercial forests are defined as those lands not withdrawn for non-timber purposes which are capable of growing 20 cubic feet of wood per year of desirable species.

**/ 2,4,5-T is sometimes used for other forestry herbicide operations, including rehabilitation or species conversion, fuel break maintenance, and timber stand improvement. The major forestry uses of 2,4,5-T are site preparation and release, which are the focus of this analysis.

Approximately 2 million acres of forests currently receive site preparation while approximately 1.5 million acres receive release treatments. 2,4,5-T is used for about 20% of the site preparation (1.16 million pounds on 414,370 acres) and about 51% of release treatments (1.48 million pounds on 749,320 acres). Other chemicals are often used for both practices, as well as hand, mechanical, and prescribed burning treatment.

Herbicides are applied by broadcast foliage spray (aerial and ground) and by individual stem applications. Because it is selective and does not injure conifers, 2,4,5-T is the only herbicide widely applied by broadcast methods. Broadcast foliar applications account for 89%, and the remainding 11% are individual stem treatments. Other registered chemicals are applied almost entirely by stem treatments since they are damaging to conifers.

Site preparation with other chemicals generally costs $20-50/acre, which is somewhat more than with 2,4,5-T treatment. Mechanical methods may range from $45-$200/acre. Prescribed burning is effective at $3-$14/acre in the East. In the Pacific Northwest, burning costs $85-$225/acre, is very risky and hard to control, and may be restricted because of smoke management regulations. Severe sprouting after fires requires 1-2 release treatments in nearly all cases. Mechanical or combination methods provide the best sites for reforestation. They are limited, however, to gentle terrain and may cause erosion on sloping lands. They can sometimes be incorporated with logging slash cleanup on western forests, reducing the costs of new stand establishment.

Release of young conifer stands from hardwood competition can be accomplished only by chemical or hand methods. Chemicals, principally 2,4,5-T, provide some control of sprouting which manual methods do not. Thus, manual weeding may require two or more treatments in severe cases. Only two other chemicals, fosamine and glyphosate (registered only in Washington and Oregon), provide this selective control. Their costs are $30-$250/acre. Aerial applications of 2,4,5-T cost $10-$20/acre in the South and $10-$75 in the West. Hand methods may be used to a limited extent where labor is available, at costs of $30-$200/acre or more depending on density and size of hardwoods. No chemical other than 2,4,5-T is presently available in the eastern U.S. where 67% of the acreage of the 2,4,5-T for release work is accomplished.

Intensive management of young confier stands is practiced primarily by public agency managers or timber companies, rarely by small owners. Site preparation is normally tied to harvest cutting which in turn is dependent upon marketing commitments (e.g., U.S. Forest Service) or company raw material needs (industry).

Where current site preparation plans include 2,4,5-T, some alternative method will likely be used. Costs may increase from 20-200% for most alternatives now available. If budgets are inflexible, harvest cutting may be reduced (USFS or state agencies) in order not to accumulate acres needing site preparation.*/ Industry owners are more likely to continue planned harvests and absorb the increased site preparation costs.

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*/ The U.S Forest Service is required to reforest havested acres within three years under the National Forest Management Act of 1976.

Release activities are less dependent on other activities and can ordinarily be postponed for a few years, at the increasing sacrifice of some future production. If budgets are relatively fixed, some of the more productive acres will be treated in 1979-80 where alternatives are not too costly. Because of the lack of a selective herbicide other than 2,4,5-T for use on pine stands (especially in the South and North), it is anticipated that approximately 60-70% of these stands in need of release will go without treatment during 1979-80. In the West, about 3/4 of needed release will be scheduled using other herbicides, although full adjustments may be delayed to the second year.

Immediate impacts on users would occur in two forms: increased costs and reduced future productivity. Cost increases for site preparation would range from \$20-\$200/acre depending on the method chosen. For the first year, release costs would go up in the West by \$10-\$200/acre on those acres where young stands are threatened with imminent loss to weeds, possibly 20% of the 246,000 acres currently released with 2,4,5-T. The second year could see the use of substitutes on the entire 1/4 million acres, as budgets are adjusted to new costs. Current total release costs in the South would drop as many acres (65%) are left without treatment. However, there would be increased release costs as release is attempted at a later time, as well as productivity losses in the future.

Reduced future productivity may be reflected in harvest cut adjustments where budgets cannot accomodate the increased costs of alternate methods. The U.S. Forest Service is presently considering proposals for about 34,000 acres of 2,4,5-T applications on National Forests for 1979 (USFS 1979a). Because of recent policies on the use of 2,4,5-T, these proposals are to cover situations where no alternative weed control appears feasible. The loss of 2,4,5-T for these situations could conceivably cause a reduction of FY 79/80 timber sale offerings to avoid accumulations of future problem areas. However, it is not likely to do so, as discussed below.

Since weed control occurs early in the life of forest stands, the economic consequences of reduced control are delayed until harvest time 30-125 years in the future. However, substained yield management (as required on National Forests by the Multiple Use-Sustained Yield Act of 1960) requires a matching of harvest to anticipated growth of the entire forest. Any loss in productivity due to decreased weed control would, on National Forests, be reflected in reduced harvests. Obviously this effect would accumulate for each succeeding year of reduced weed control. These adjustments are normally made at 10-year intervals for most National Forests, and may not be reflected in immediate harvest reductions during a one or two year suspension.

Private industry would likely accept the losses in ultimate harvest as they occur in the future, with no immediate reduction in harvest schedules (API/NFPA rebuttal to the RPAR on 2,4,5-T, 1978).

Suspension would increase annual control costs by $13.5 million if all 1.16 million acres now treated with 2,4,5-T were treated with alternatives (USDA/States/EPA, Feb. 15, 1979). This is an increase of $11.64 per treatment acre. For site preparation, the increase in cost would average less than this, e.g., $5-$10 per acre; for release, it would be generally much higher due to increased use of the more costly manual methods, e.g., $30-$200 per acre in many cases. No overall average cost impact can be computed on a percentage basis with current information. It is unlikely that alternative control plans would be in full effect until the second year of suspension. The first year effects would likely be 50 to 70% of these costs($7-$10 million), with added spending in later years to make up for operations postponed the first year.

These added control costs due to suspension would be in addition to the value of any actual growth losses associated with delayed or less effective site preparation and/or release treatments. A minor yield loss is projected for Loss the first year of suspension (less than 0.2 percent of U.S. softwood production) . This would increase in the second year to about 0.5 percent. These losses in yield, if realized would have an estimated reduction on forestry income of $9.6 million the first year of suspension and about three times this amount the second year ($29 million) under the assumptions of the USDA/ State/EPA 2,4,5-T Assessment Team Report [USDA/States/EPA, Feb. 15, 1979].

The total impact, including both increased control cost ($7 to $10 million) and yield losses, if realized (up to $9.6 million) would be in the range of $10 to $17 million. (If all 2,4,5-T acres were treated with alternatives, which is unlikely, the total impact would be about $21.3 million the first year.) For the second year, the combined impact would be more, totalling $36 to $39 million ($7-$10 million plus $29 million in eventual yield losses) . While significant, these impacts are rather nominal within the context of overall forestry industry of the U.S.

Effects on wood product prices would only occur if a decision were made by the U.S. Forest Service to curtail timber sales in the near future. The limited impacts of suspension on production would not necessitate a significant increase in wood product prices.

The economic impacts of suspension of the forestry use for 3 1/2 months during emergency proceedings would be nominal even though conifer release treatments in the Pacific Northwest, are generally applied in the spring, before bud break which occurs by March. Some such treatments may have already been made and delay of others for two to four months during a suspension proceeding is of little significance.

(2) Rights-of-Way

2,4,5-T is used to control woody and herbaceous plants on rights-of-way (railroad, highway, electric transmission, and pipeline) which could interfere with the functioning of the system (e.g., weed encroachment on highways), threaten the system's equipment, and/or interfere with inspection and maintenance of the system. 2,4,5-T is considered to provide longer control of pest plants than other control methods without harming grass and other vegetation desirable for erosion control, wildlife shelter, and aesthetics.

Chemical, manual, and mechanical methods of control are used in various combinations on rights-of-way acres, depending on the terrain, availability of labor, type of equipment and species type and density. Combining control methods is a common practice on rights-of-way acreage.

A relatively large number of acres apparently receive no vegetation management. Only about one-fourth of electric utilities, railroads, pipelines, and highway departments have all acres in management programs.

For highways and pipelines, mechanical methods are used on more acres than any other method. Manual is used on most acres of electric acreage and is frequently employed as follow-up treatment to supplement chemical control. Somewhat less than 1/3 of all rights-of-way acreage are estimated to be treated by manual methods. Chemicals other than 2,4,5-T are more common on railroad acreage. Acres treated with chemicals are most likely to be acres where mechanical control is difficult and where other alternatives are expensive or relatively ineffective.

About 683,000 rights-of-way acres are treated with 2,4,5-T on the average of once every four years, or 2.7 million acres total. An estimated 3.8 million pounds a.e. are used annually. Only a small percentage of rights-of-way vegetated acres are treated: 6.6% of railroad (127,000 acres), 9.4% of electric (465,000 acres), 4% of pipeline (22,000 acres), and 0.8% of highway (68,000 acres). Usage is believed to be mainly in the eastern and far northwestern parts of the continental U.S.

Other chemicals are also currently used on many rights-of-way acres, including dicamba, 2,4-D, dichlorprop, and picloram. Almost 13% of the highway, 25% of electric utilities, 45% of railroad, and 5% of pipeline acreage is treated annually with other chemicals (which may include some non-herbicides).

2,4,5-T is $1.00 to $3.00 more expensive per application than other chemicals, for aerial, selective basal, and stump spray, which account for about 65% of annual acreage treated. For ground broadcast or selective foliar treatment, 2,4,5-T is cheaper ($2.00 to $19.00 in one case). The major economic advantage of 2,4,5-T is in the longer period of control it is said to provide. Generally, mechanical and manual methods are much more expensive than chemical methods.

With use of 2,4,5-T suspended, rights-of-way managers would be faced with two main choices: (1) use alternative chemicals on acres scheduled for treatment or (2) postpone any treatment to see if 2,4,5-T would be available the next year. They would most likely use alternatives on at least some acres, in the Southeast and Pacific Northwest, where plant growth is rapid. The percentage of acres treated with alternatives would vary by right-of-way type and would probably be lower for railroads and highways, since they appear to be more flexible in treatment schedules.

If some acres are not treated during the first year following suspension, they would probably be added to scheduled treatments in the second or third year. It can be assumed that many managers would continue treating acres each year as scheduled with alternative herbicides because of increases in size and density of pest plants. If so, annual costs for vegetation management for highways and railroads would increase by about $133,000 and $1,845,000, respectively, if they treat all acres with alternative herbicides.

Costs for electric and pipeline rights-of-way would temporarily decrease by an estimated $680,000 and $28,000, respectively, each year during suspension, mainly because of the high proportion of aerial and selective basal applications. These applications are lower in cost than 2,4,5-T but must be repeated more often. There would be a net cost increase over time due to suspension only if 2,4,5-T is not available after the suspension period, i.e., if it is cancelled.

The overall net cost increase for all rights-of-way types due to suspension only would be about $1.3 million per year during the 1979-1980 period. These changes in vegetation management costs are not expected to impact industry net revenue or operating costs significantly. Increased vegetation management costs due to suspension would be less than 0.1 percent of operating expenditures for highways and railroads.

Impacts at the consumer level due to suspension of highway and railroad uses are estimated at less than \$0.03 per household per year. This is based upon the annual cost impacts noted above (\$2.0 million) and the number of households in affected regions. No significant macro-economic impacts would be expected from suspension of 2,4,5-T on rights-of-way.

In view of the limited economic impacts from a two-year suspension period, economic impacts during the 3 1/2 months required for a suspension proceeding would be of no economic significance on rights-of-way.

(3) Pasture

2,4,5-T is used to control a wide variety of wood and herbaceous weeds in pastures*/ throughout the U.S. Weed control in pastures is economically sound where the cost of control is exceeded by the value of increased forage yield due to suppression of competitive non-forage vegetation. It is also practiced for reasons of long-term pasture maintenance and cheaper fence maintenance. Weed control by means of 2,4,5-T is now practiced annually on about 1% of U.S. pasture acreage (1.0 million of the estimated 101 million acres of pastureland in the U.S (48 states)). This use includes approximately 500,000 pounds of active ingredient of 2,4,5-T annually. Generally, 2,4,5-T is applied in pastures as a spot treatment with backpack or hand-held sprayers, although some broadcast treatments are also used. In contrast to range**/, little 2,4,5-T is aerially applied to pastures because landowners rarely allow weed infestations to become sufficiently dense to justify aerial application.

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*/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

There appear to be effective chemical, manual, and/or mechanical control alternatives for all species in all regions, although no single set of alternatives can be used on all weed species or in all parts of the country. Thus, alternatives such as picloram, dicamba, undiluted 2,4-D, and hand labor can generally provide the same level of control as 2,4,5-T, although at higher rates of application and/or higher expense. Since equally effective alternatives are available, no yield impacts are expected during the 2-year

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**/ Range is non-pasture grazing land on which forage is produced through native species, or on which introduced species are managed as native species. This precludes land on which regular cultural practices of the nature contained in the pasture definition.

suspension period. On those acres where the conditions and type of weed permit use of an alternative which is not more expensive than 2,4,5-T, it is likely that these alternatives will be fully employed. Here no negative economic impact would be experienced.

On those acres where the use of alternatives will cost more than scheduled 2,4,5-T treatments, treatment may be delayed, dispensed with entirely, or the more expensive alternative employed. Since treatments with 2,4,5-T are generally effective for 5 to 10 years, the timing of control is largely voluntary. Therefore, delay during the suspension period may be practical on much of the acreage scheduled for treatment. Treatment may be entirely dispensed with on acres scheduled for 2,4,5-T treatment which only marginally require such treatments.

Presently the chemical costs of 2,4,5-T treatments are about $2.00 per acre (or about $2.0 million on 1.0 million acres). The chemical cost of alternatives is estimated at about $6.00 per acre. Thus, for each acre treated with alternatives during suspension, the cost impact would be $4.00. If all 1.0 million acres were treated, the cost impact would be $4.0 million. Since treatment is a given year is quite optional during the 5 to 10 year treatment cycle on pasture, as many as one-half to one-fourth might defer treatment in 1979/1980. This would reduce the impact to $2.0 to $3.0 million per year during suspension.

The economic impacts of a two-year suspension of the pasture use of 2,4,5-T would be of no consequence on a national basis. It would be of significance to the individual owners or operators whose pastures are due for immediate treatment and on which more expensive alternatives must be used. These impacts would be of limited local/regional concern.

In view of the limited economic impacts of a two-year suspension, the economic impacts during the 3 1/2 months required for a suspension proceeding would be of no economic significance.

V. PROCEDURAL MATTERS

This order directs the emergency suspension of the forestry, rights-of-way, and pasture uses of 2,4,5-T. Registrants affected by emergency suspension actions may request an expedited hearing before the Agency. This section explains how to request an expedited hearing, the consequences of requesting or not requesting an expedited hearing, and the procedures which govern an expedited hearing in the event one is requested.

A. Procedures for Requesting a Hearing

(1) Who May Request a Hearing and When the Request Should Be Made

Registrants of 2,4,5-T products registered for the forestry, pasture, or rights-of-way uses of 2,4,5-T may request a hearing on these specific registered uses of 2,4,5-T within five days after receipt of this opinion and order.

(2) How to Request a Hearing

Registrants who request a hearing must follow the Agency's Rules of Practice Governing Hearings (40 CFR, Part 164). These procedures specify, among other things: (1) that all requests for a hearing must be accompanied by objections that are specific for each use for which a hearing is requested [40 CFR 164.121(a) and 164.123(b)] and (2) that all requests must be filed with the Office of the Hearing Clerk within the applicable five (5) days [40 CFR 164.121(a)]. Failure to comply with these requirements will automatically result in denial of the request for a hearing.

Requests for hearings must be submitted to:

Hearing Clerk (A-110)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

B. Consequences of Filing a Hearing Request

Under FIFRA Section 6(c)(3) the emergency suspension order becomes effective immediately and, unless stayed, continues in effect until completion of the expedited hearing and issuance of a final order of suspension. The statute provides that where an administrative hearing is requested, the emergency order is subject to District Court review on the emergency finding. The final suspension order issued by the Administrator after a hearing may keep the suspension in effect, modify it, or terminate it. A final suspension order issued following a hearing is then reviewable in the Court of Appeals.

The statute provides that if a hearing is requested on the Administrator's emergency suspension actions regarding 2,4,5-T before the end of the five-day notice period, the hearing stage is to begin within five days after receipt of the request, unless the registrant and the Agency agree that it shall begin at a later time. No party, other than the registrant and the Agency, is to participate, except that any person adversely affected may file briefs within the time allowed by the Agency's rule. Hearings on emergency suspension, like hearings on ordinary suspension, are subject to the provisions of subchapters II of Title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. The presiding officer has ten days from the conclusion of the presentation of evidence to submit recommendations to the Administrator, who in turn has seven days to issue a final order on the issue of suspension.

C. Consequences of Not Filing a Hearing Request

Under the statutory scheme, if there is no request for a hearing on the Administrator's suspension actions within the five-day notice period, the emergency suspension order becomes a final suspension order, which remains in effect until the conclusion of the cancellation proceedings, unless modified or vacated sooner (40 CFR 164.130). Court review of an emergency suspension order, including the special review before the District Court discussed in Part II is available only if an administrative hearing has been requested within the applicable five-day period [FIFRA Section 6(c)(2), 6(c)(3)].

D. Supplementary Procedures

EPA's rules of procedures for expedited hearings are set forth at 40 CFR Part 164, Subpart C. I do not know if a hearing will be requested on these suspensions. If it is, however, I am establishing the following procedures to supplement the existing regulations in governing its conduct.

1. A deadline is being established for the completion of all hearing procedures and the rendering of a recommended decision under 40 CFR 164.121(j). That deadline is 90 calendar days from the first prehearing conference, which shall be held in accordance with the time requirements described below.

2. I am naming certain EPA employees to serve as a hearing panel in any hearing arising out of this notice (see Appendix A).

I am naming certain additional persons to be available to provide technical advice and staff support to the hearing panel (see also Appendix A). If questions arise at the hearing which persons in this category are uniquely qualified to assess, they may be called on to serve on the panel either in addition to, or in substitution for, the three panel members named above.

The panel will conduct the hearing and submit a recommended decision to me under 40 CFR Section 164.121(j). None of the persons named above is subject in the normal course of their duties to the supervision or direction of any employee or agent of EPA who is a member of the Agency trial staff named below. See 5 U.S.C. Section 554(d)(2).

Since 5 U.S.C. Section 554(d)(1) provides that those presiding at adjudicatory hearings may not "consult a person or party on a fact in issue [in the course of preparing their decision] unless on notice and opportunity for all parties to participate," neither myself nor my appellate staff will consult with the panel or its supporting staff on any matters involving this case from the date of notice until a recommended decision is issued. Members of my appellate staff are also listed in Appendix A. We will conduct an independent review of the questions presented on appeal of any recommended decision. However, in doing this we will feel free to consult with the hearing panel and the support panel, since they will have conducted the initial proceedings and brought expert knowledge to evaluating the record.

The following Agency bureaus or divisions, and their staffs, are designated to perform all investigative and prosecutorial functions in this case: Office of the Deputy Administrator*/, Office of Toxic Substances, the Office of General Counsel, and the Office of Enforcement.

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*/ The Deputy Administrator may properly be included in the trial staff since the prohibitions of 5 U.S.C. Section 554(d) do not apply to "the agency". Her inclusion is necessary if guidance on general policy matters is to be available to the trial staff and, to free a high agency official to talk to outside interested persons about the questions involved without the constrains otherwise imposed by the ex parte provisions of the APA and the Government in the Sunshine Act. The Deputy Administrator will take no part in the detailed work of preparing and presenting the Agency's case.

From the date of this notice until any final decision, no member of the hearing panel, its support staff, my appellate staff, or myself, shall have any *ex parte* contact with any trial staff employees, or any other interested person not employed by EPA, on any of the issues involved in this proceeding. However, persons interested in this case should feel free to contact any other EPA employee, including both trial staff and persons not explicitly named as panel members or assistants, with any questions they may have.

3. I am directing the hearing panel to proceed as follows to streamline proceedings in this case.

a. My findings on imminent hazard and emergency for suspended uses of 2,4,5-T together with supporting information are in my opinion and order, which is available for inspection in the Office of the Hearing Clerk. Additional supporting information, including references cited in the opinion and orders, is also available for inspection in the Office of the Hearing Clerk. Together these documents constitute the Agency record in this matter.**/ EPA has also attempted to put this information in perspective through a narrative summary and analysis.

**/ Some of the documents in the record may be entitled to confidential treatment under FIFRA Section 10, as amended. Parties to the hearing may have access to such documents if appropriate protective arrangements are made. See also the footnote to this Order concerning confidentiality of data [in Section IV.A.(1)(a) i)].

b. The scheduling of any hearing, particularly in its earlier stages, involves a balancing between the need to conduct an expeditious hearing and a concern that the hearing not proceed too far before the identity of those registrants requesting a hearing is established. In arranging for the first prehearing conference, I have attempted to accommodate both interests. The hearing panel shall convene the first prehearing conference within five days after receipt of the last request for a hearing by a registrant or 15 days after the issuance of my opinion and order, whichever comes earlier. The 15 day maximum should ensure that all registrants wishing to participate in the hearing have been given ample time to file a hearing request after receiving notification of my suspension actions.

c. Within ten days from the first prehearing conference, any person requesting a hearing shall submit focused written comments on this opinion and order consisting of a counterstatement of proposed findings on the issue of imminent hazard presented by 2,4,5-T together with supporting information. A narrative summary explaining its bearing on the case should also be included.

d. The Agency trial staff shall have seven days thereafter to file supplemental information and comments.

(2) Requests for cross-examination shall be granted only if all of the following showings are made:

i. The request concerns factual matters. Cross-examination will not be granted on matters of policy or law.

ii. The factual matters are legitimately in dispute in light of the record.

iii. The factual matters are material to the decision to be made.

iv. Cross-examination is the most efficient way of resolving the dispute over these factual matters (as opposed to such alternatives as production of further information, or informal conferences).

v. There is a reasonable expectation that cross-examination will resolve the issue of material fact in a way likely to influence the final decision.

g. The testimonial phase of the hearing shall begin three days after issuance of the order setting the hearing schedule. At the hearing, the panel shall take an active role in the development of the record through questioning of witnesses and by issuing procedural orders where necessary.

(2) Requests for cross-examination shall be granted only if all of the following showings are made:

i. The request concerns factual matters. Cross-examination will not be granted on matters of policy or law.

ii. The factual matters are legitimately in dispute in light of the record.

iii. The factual matters are material to the decision to be made.

iv. Cross-examination is the most efficient way of resolving the dispute over these factual matters (as opposed to such alternatives as production of further information, or informal conferences).

v. There is a reasonable expectation that cross-examination will resolve the issue of material fact in a way likely to influence the final decision.

g. The testimonial phase of the hearing shall begin three days after issuance of the order setting the hearing schedule. At the hearing, the panel shall take an active role in the development of the record through questioning of witnesses and by issuing procedural orders where necessary.

h. At the end of the initial testimonial phase, the hearing panel may permit the introduction of additional information designed to rebut the contentions made by opposing parties.

i. The panel may revise any of the procedural provisions of this notice other than the overall 90-day deadline for rendering a recommended decision the time for which starts running after the first pre-hearing conference.

A discussion of some aspects of these procedures follows:

(1) Deadlines

Deadlines for completing proceedings under FIFRA have been twice endorsed by the National Academy of Sciences [National Academy of Sciences, Decision Making in the Environmental Protection Agency, Vol. II, p. 84 (1977); National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment, p. 30 (1975)].

In addition, Congress has demonstrated a concern for speedy action where suspensions based on a potential threat to human health are concerned. It has required a hearing on such a suspension to begin five days after it is requested*/, and has allowed ten and seven days respectively for preparation of the initial and final decisions once the hearing is over [FIFRA Section 6(c)(2)]. FIFRA was amended in 1975 to require consultation by EPA with the Department of Agriculture and a scientific advisory panel before taking action in many cases; suspensions based on human health grounds, however, were exempted from those requirements to allow speedy action where speedy action was desirable [121 Cong. Rec. H 9895-96 (daily ed. Oct. 9, 1975); 121 Cong. Rec. Section 19820-21 (daily ed. Nov. 12, 1975)].

Deadlines for completing the hearing have been imposed in prior suspensions. See, e.g., *In re: Vesicol Chemical Co., et al.*, 41 F.R. 7552, 7553 (Feb. 19, 1976) [Notice of Intent to Suspend Heptachlor and Chlordane], and *In re: Dibromochloropropane*, 42 FR 48915 (Sept. 26, 1977). [Notice of intent to suspend and conditionally suspend registrations of pesticide products]. The requirements set forth in this order simply carry forward that practice.

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*/ I do not regard the procedures set forth below as inconsistent with this directive. What concerned Congress was plainly that the hearing *stage* of Agency decision-making begin promptly, not that the oral hearing itself start unconditionally in less than a week. To interpret the law otherwise would forbid the use of such accepted aids to efficient decisions as prehearing conferences in precisely the cases where efficiency is most required.

(2) Use of a Panel

Despite the need for speedy action, the issues involved in suspension are complex. Under the statute, a judgement of "imminent hazard" must be based on consideration of costs and risks of all types [FIFRA Sections 2(l), 2(bb)]. Given the necessary time constraints and the preliminary nature of suspension as a remedy, factual certainty may be elusive. "[T]he function of the suspension decision is to make a preliminary assessment of evidence, and probabilities, not any ultimate resolution of difficult issues" [Environmental Defense Fund, Inc. v. EPA, 510 F.2d. 1292, 1298 (D.C. Cir. 1975), quoting from Environmental Defense Fund, Inc. v. EPA, 465 F.2d. 528, 537 (D.C. Cir. 1972)].

Arriving at even such a preliminary assessment can present formidable difficulties. Considering risks, questions can arise concerning the dispersion and persistence of the pesticide in the environment and certain parts of it, the conduct of animal feeding studies, the meaning of those studies for human health, the validity of relevant epidemiological studies, the reliability of using known human exposure from one use pattern as a predictor of potential human exposure in other use patterns, and finally on what the upper and lower boundaries of any risks may be and how firmly they are established. Considering benefits, questions can be raised about the extent of use, the availability, practicality, and effectiveness of substitutes both now and in the future, and the range of the probable economic impacts of a temporary ban on the pesticide, or some use of it, in the light of all these factors.

The job will be easier and better performed, if I am allowed to rely directly on the talents of EPA employees with expert knowledge of the technical fields involved and with the professional ability to assess problems arising in them. I believe it is for this reason that Congress has provided that those presiding over suspension hearings need not be hearing examiners*/.

(3) Conduct of the Hearing

Overuse of cross-examination and courtroom formalities, I believe, has made many FIFRA proceedings far longer than was consistent with any rational purpose. The overwhelming bulk of legal analyses by those who have studied the problem, and EPA's own experience demonstrate that scientific and economic issues can be clarified by the exchange of written material far more efficiently than through courtroom hearings. I am directing that written submissions be used here to focus the issues in an attempt to implement those lessons. At the same time, particularly where Congress has explicitly called for formal hearings, the accompanying rights to reasonable cross-examination and oral presentation must be preserved.

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*/ The fact that more than one person will preside is of no legal significance. Even when 5 U.S.C. Section 556 requires a hearing to be presided over by an examiner (or a person representing the Agency), it also specifies that "one or more" of those qualified may preside.

All three elements of these supplementary procedures are meant to work together. The use of a panel will ensure that expert knowledge is indeed brought to the task of making a decision. The provision for preliminary written submissions will allow that panel to screen the issues and narrow the formal part of the hearing down to those that are legitimately in dispute and suited to adjudicatory resolution. Finally, setting a schedule for decision will help ensure that the potential gains in efficiency represented by the first two reforms are realized in practice.

Douglas M. Costle
Administrator

Dated: FEB 28 1979

APPENDIX A

HEARING PANEL

Charles Gregg, Chairperson
William Brungs
Robert Coughlin

TECHNICAL SUPPORT PANEL

Robert Chapman, M.D.
Neil Chernoff
Arnold Kuzmack
Dr. James Lichtenberg

ADMINISTRATIVE APPELLATE PANEL

Ronald L. McCallum
Charles R. Ford
Dr. Edwin H. Clark
Ms. Mary Ann Massey
Dr. Richard M. Dowd
Dr. Stephen J. Gage

2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T)

Notice of Intent to Cancel the Forestry, Rights-of-Way, and Pasture Registrations of Pesticide Products Containing 2,4,5-T

I. INTRODUCTION

I am today issuing an emergency order suspending immediately the forestry, rights-of-way, and pasture uses of pesticide products containing 2,4,5-T, and a statement of reasons. Section 6(c)(1) of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) [7 U.S.C. Section 136d(c)(1)] provides that a suspension order cannot be issued unless a notice of intent to cancel the registrations or change the classifications of the pesticide products concerned has already been issued or is issued with the suspension order. For the reasons set forth below, I find that the continued use of pesticide products containing 2,4,5-T on forests, rights-of-way, and pastures, in accordance with current use instructions, appears to pose an unreasonable risk to humans. I am therefore announcing my intention to cancel these three registered uses of 2,4,5-T under Section 6 of FIFRA [7 U.S.C. Section 136(d)(b)].

II. LEGAL AUTHORITY

Section 6(b) of FIFRA [7 U.S.C. Section 136d(b)] authorizes the Administrator to issue a notice of intent to cancel the registration of a pesticide or to change its classification if it appears to him that the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Thus, the Administrator may cancel the registration of a pesticide whenever he determines that it no longer satisfies the statutory standard for registration which requires (among other things) that the pesticide "perform its intended function without unreasonable adverse effects on the environment" [FIFRA Section 3(c)(5); 7 U.S.C. Section 136a(c)(5)]. He may also change the classification of any use of a pesticide if he determines that such a change "is necessary to prevent unreasonable adverse effects on the environment" [FIFRA Section 3(c)(2); 7 U.S.C. Section 136a(d)(2)]. "Unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [FIFRA Section 2(bb); 7 U.S.C. Section 136(bb)].

The burden of proof for establishing the safety of a pesticide product to support a decision concerning registration or continued registration rests at all times on the proponent of registration [Environmental Defense

Fund v. Environmental Protection Agency, 465 F.2d 528, 532 (D.C. Cir. 1972); EDF v. EPA, 510 F.2d 1293, 1297 (D.C. Cir. 1975); EDF v. EPA, 548 F.2d 998, 1004 (D.C. Cir 1976)].

In effect, FIFRA requires the Administrator to weigh the risks and benefits associated with each use of a pesticide. If he determines for any particular use that the risks exceed the benefits, he must then determine whether those risks can be sufficiently reduced (so that they are outweighed by the benefits) by the imposition of restrictions upon use through changes in the labeling and/or by the classification of the use for restricted use. If he determines that adequate risk reduction cannot be achieved by such regulatory measures, the registration of the pesticide for that use must be fully cancelled.

III. REASONS FOR INITIATING PROCEEDINGS TO CANCEL

A. Risks

On the basis of data available to the Agency, I conclude that 2,4,5-T and/or its contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), create a serious health risk for humans and that human exposure to 2,4,5-T and/or its contaminant, TCDD, is cause of considerable concern.

The Agency has reviewed numerous studies in which industrial, academic, and government scientists have reported that TCDD and/or 2,4,5-T contaminated with TCDD produce fetotoxic, teratogenic, and carcinogenic effects in test animals that have been exposed to these chemicals. The occurrence of these adverse effects in test animals following exposure to 2,4,5-T and/or TCDD indicates that humans who are exposed to 2,4,5-T may experience comparable effects. Concern for the health of humans who may be exposed to 2,4,5-T and its contaminant, TCDD, is heightened because scientists have not demonstrated that there is a level of exposure that has no adverse effects in humans.[1/]

A recent EPA-sponsored epidemiological study shows human miscarriages in Alsea Oregon to be related to the use of 2,4,5-T, both geographically and temporally. Specifically, the study indicates that women who live in an Oregon area (Study area) where 2,4,5-T is used for forest management experience miscarriages more frequently than do women who live in other Oregon areas where there is little or no known use of 2,4,5-T or other dioxin-containing phenoxy herbicides. Most significantly, the data generated through this study show that an increase in the frequency of miscarriages for women in the Study area is greatest two months after the period when 2,4,5-T is used in this area, and that there is a close correlation between the amount of 2,4,5-T used by month and the size of the increase in the frequency of miscarriages two months later. These data showing that humans who reside in areas where 2,4,5-T is used experience

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[1/] A Committee of the National Research Council of Canada recently agreed with the authors of the World Health Organization's monograph on TCDD that "for TCDD a no-effect level for man could not be established" (NRCC 1978).

adverse effects comparable to those observed in laboratory animals that have been exposed to 2,4,5-T and/or TCDD have prompted the Agency to analyze the risk potential to other populations who live and/or work in areas where 2,4,5-T is used and who therefore may be exposed to this pesticide product.

The Agency concludes that it is prudent to assume that individuals living in or frequenting areas where the forestry use of 2,4,5-T occurs may experience exposure to 2,4,5-T qualitatively similar to that experienced by the Alsea women, and may suffer the adverse effects which 2,4,5-T and/or TCDD produces. The Agency also concludes that individuals, living in or frequenting areas of 2,4,5-T use where the use patterns create similar or greater possibilities for exposure than the forestry use, run a potential risk of adverse effects from 2,4,5-T exposure. Such use patterns include, without necessarily being limited to, the rights-of-way and pasture uses of 2,4,5-T.

The Agency has identified pesticide applicators and persons involved in pesticide application support activities, and persons living in or frequenting areas of 2,4,5-T use as the principal groups of individuals who may be exposed as a result of forestry use, rights-of-way use and pasture use of 2,4,5-T. Based upon animal data and other information (including the recent Oregon study), individuals exposed to 2,4,5-T may suffer adverse reproductive effects or develop cancer.

C. Determination of Benefits

2,4,5-T is registered for control of woody and herbaceous plants on rights-of-way, forestry, range, pasture, and rice. The uses subject to this action (rights-of-way, forestry, and pasture) comprise about 74% of the estimated 9.3 million pounds of 2,4,5-T active ingredient used annually in the U.S. Rights-of-way usage (3.8 million pounds) is the single largest use, comprising an estimated 41% of total annual usage; forestry (2.6 million pounds) and pasture usage (500,000 pounds) account for about 28 and 5%, respectively, of annual 2,4,5-T usage.

The Agency has evaluated the potential economic impacts of cancelling the forestry, rights-of-way, and pasture uses of 2,4,5-T. The Agency's analysis indicates that the cancellation of 2,4,5-T (and silvex) for forestry, rights-of-way, and pasture uses would not, in general, significantly affect U.S. production or prices of commodities and services from these sectors. Impacts on productivity and costs would generally be temporary and regional in nature and of minor significance at the national level. The major exception to this is the forestry uses of 2,4,5-T for enhancing growth of conifers. Long-term yields could be affected significantly if effective alternatives are not available in a few years.

My conclusion that the overall national impact of cancellation would not be substantial stems from three considerations: (1) chemical, mechanical, or manual alternatives to 2,4,5-T are in use, and in many cases these alternatives would not add significantly to commodity/service production costs; (2) new chemicals (or adaptations of existing ones) may become available as replacements for 2,4,5-T. Some promising replacements are in use under experimental use permits in individual states, and others are already registered in some states; and (3) treatment may be discontinued altogether where it is of marginal utility.

The economic impact of cancellation on each of the three uses is examined in the following discussion.

(1) Forestry

There are about 500,000,000 acres of commercial forests[2] in the U.S. of which 1.16 million acres (0.23%) are treated annually with 2,4,5-T. This herbicide can be used at either or both of two stages in the production[3] of conifers (softwoods): (1) preparing sites for reforestation and (2) releasing young trees from hardwood competition. Each operation is undertaken once in the 50-year cycle of a softwood stand. 2,4,5-T is one of several chemical and non-chemical control methods used, individually or in combination, for site preparation and release.

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[2] Commercial forests are defined as those lands capable of growing 20 cubic feet of wood per year of desirable species which are not withdrawn for non-timber purposes.

[3] 2,4,5-T is sometimes used for other forestry herbicide operations, including rehabilitation or species conversion, fuel break maintenance, and timber stand improvement. The major forestry uses of 2,4,5-T are site preparation and release, which are the focus of this analysis.

Cancellation of 2,4,5-T will have little impact on the cost of preparing sites for reforestation following harvests. Non-chemical methods are effective in many areas. Where chemical control is most appropriate, 2,4,5-T is only one of several alternative chemicals used (picloram, 2,4-D, dicamba, Atrazine, and Banvel), although it is one of the least costly.

The long-term unavailability of 2,4,5-T for release of hardwood competition for conifer cultivation could have a significant long-term impact on tree growth if comparably effective alternatives (chemical or otherwise) are not available. 2,4,5-T has a wide sprectrum of weed-control efficacy but does not damage young conifers, when properly applied. Moreover, 2,4,5-T's cost is low. Only 2,4,5-T and, in some instances, 2,4-D and two state-registered chemicals are effective on the weed species requiring control by broadcast foliar sprays. In the short run, the economic impact of loss of 2,4,5-T would be limited primarily to the increased cost of alternatives applicable to those acres on which alternatives (rather than no treatment) would be applied.

(2) Rights-of-Way

2,4,5-T is used to control woody and herbaceous plants on vegetated rights-of-way (railroad, highway, electric transmission, and pipelines). 2,4,5-T provides longer control of pest plants than other control methods without harming grass and other vegetation desirable for erosion control, wildlife shelter, and aesthetics. The rights-of-way use (3.8 million pounds annually) comprises 41% of the total use of 2,4,5-T.

Most rights-of-way acres are not treated by any control method. Mechanical and manual methods are more commonly used than chemical treatments. Chemicals are used to supplement mechanical methods or where control by mechanical methods is difficult or ineffective. Without 2,4,5-T, rights-of-way managers are expected to turn to other herbicides for control on a per treatment basis. Alternative chemicals are less expensive than 2,4,5-T for the aerial, selective basal, and stump spray methods of application. 2,4,5-T, however, provides longer control than do other chemicals.

Because 2,4,5-T is believed to provide control for a longer period, the major economic impact of cancellation of its use on rights-of-way is expected to be the cost of more frequent treatment. Overall changes in chemical costs are estimated at $1.27 million annually (an average of less than $2.00 per acre). It may be necessary to change from a four-year treatment cycle to a three-year cycle; this would add another $32.6 million annually (about $48.00 per acre) to increased costs.

Annual cost increases of $33.9 million (about $50.00 per acre) might, therefore, result from cancellation of this use.

Compared to total annual operating expenses for rights-of-way, these increases are insignificant. For highways and railroads, for example, these estimated increases in vegetation management costs would be less than 0.1% of total operating expenditures.

(3) Pasture

2,4,5-T is used to control a wide variety of woody and herbaceous weeds in pastures[4/] throughout the U.S. Weed control is economically sound in pastures where the cost of control is exceeded by the value of increased forage yield due to suppression of competitive non-forage vegetation. Typically, use of 2,4,5-T for weed control is practiced only on spots or limited portions of the farmer's pasture, rather than on the entire acreage. Weed control in pastures is also practiced for reasons of long-term pasture maintenance and cheaper fence maintenance. Weed control by means of 2,4,5-T is now practiced annually on about 1.0 million of the estimated 101 million acres of pastureland in the U.S.

[4/] Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.

Chemical, mechanical, and manual alternatives can generally provide the same level of control as 2,4,5-T for this use, but the cost of alternatives is higher than the cost of using 2,4,5-T. Since effective alternatives are generally available, no significant yield or animal production impacts would result from cancellation.

On those acres where the use of alternatives will cost more than 2,4,5-T treatments, users will incur increased costs. The increased annual costs generally will be about $4.00 per acre on those acres where alternatives are used ($6.00 compared with $2.00 for 2,4,5-T). Total cost impacts would be $4.0 million dollars if the entire 1.0 million acres treated with 2,4,5-T were treated with alternatives. The economic impacts of cancellation of the pasture use of 2,4,5-T would be insignificant to the agricultural community at the national level. No impact on consumer prices would be likely to occur.

C. Conclusion

On the basis of information currently available, I conclude that the risks posed by the continued use of 2,4,5-T on forests, rights-of-way, and pastures in accordance with current terms and conditions of registrations and commonly recognized practice appear to outweigh the benefits of these uses. For these reasons, I conclude that these uses of

2,4,5-T appear to generally cause unreasonable adverse effects on the environment [see FIFRA Section 2(bb)] when used in accordance with widespread and commonly recognized practice. Accordingly, I am hereby initiating proceedings to cancel the registrations of all pesticide products containing 2,4,5-T registered for forestry, rights-of-way, and pasture uses.

IV. PROCEDURAL MATTERS

This Notice initiates an action to cancel the registrations of the forestry, rights-of-way, and pasture uses of 2,4,5-T.[5] Under Section 6(b) and 3(c)(6) of FIFRA [7 U.S.C. Section 136d(b); 7 U.S.C. Section 136b(a)(c)(5)] registrants and other interested persons may request a hearing on the cancellation actions that this Notice initiates. This section explains the prohibition against *ex parte* communications, when and how affected persons may request a hearing, and the consequences filing or of failing to file a request for a hearing in accordance with the procedures specified in this Notice.[6]

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[5] Other procedural matters relating to the emergency actions are presented in the accompanying order suspending the uses in question.

[6] Although Section 6(b) of FIFRA generally requires prior review of and comment upon proposed notices of intent to cancel or change classification by the Secretary of Agriculture and a Scientific Advisory Panel, I am specifically authorized to waive such requirements and proceed in accordance with Section 6(c) of FIFRA whenever I find that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health. I have found that immediate suspension of the registrations of pesticide products containing 2,4,5-T is necessary to prevent an imminent hazard to human health (see Emergency Suspension Order and Notice of Intent to Suspend Uses of 2,4,5-T, issued this day). I hereby invoke my authority to waive the external review requirements.

A. Ex Parte Communications

The Agency's Rules of Practice for hearings conducted pursuant to Section 6 of FIFRA forbid the Administrator, the Judicial Officer, and the Administrative Law Judge, at all stages of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in an investigative or expert capacity, or with any of their representatives. (40 CFR Section 164.7).

Accordingly, the following Agency officers, and the staffs thereof, are designated to perform all investigative and prosecutorial functions in this case: the Office of Toxic Substances, the Office of Pesticide Programs, the Office of General Counsel, and the Office of Enforcement.

From the date of this notice until any decision, neither the Administrative Law Judge, the Judicial Officer nor myself shall have any ex parte contact or communication with any investigative or trial staff employee, or any other interested persons not employed by EPA, on any of the issues involved in this proceeding. However, persons interested in this case should feel free to contact any other EPA employee, including both investigative and trial staff, with any questions they may have.

B. Procedures for Requesting a Hearing

(1) When a Hearing Must be Requested for Cancellation Actions

Registrants affected by the cancellation actions initiated by this Notice may request a hearing within 30 days of receipt of this notice, or within thirty days of the date of publication of this Notice in the Federal Register, whichever occurs later. Any person adversely affected by the cancellation actions initiated by this Notice may request a hearing within thirty days of the date of publication of this Notice in the Federal Register.

(2) How to Request a Hearing

All registrants and other interested persons who request a hearing must follow the Agency's Rules of Practice Governing Hearings (40 CFR, Part 164). These procedures specify, among other things, that: (1) all requests for a hearing must be accompanied by objections that are specific for each use for which a hearing is requested [40 CFR 164.20(b)], and (2) that all requests must be received by the Hearing Clerk within the applicable thirty (30) day period [40 CFR 164.5(a)]. Failure to comply with these requirements will automatically result in denial of the request for a hearing.

Requests for hearings must be submitted to:

Hearing Clerk (A-110)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

C. Consequences of Filing or Failing to File a Hearing Request

If a hearing is requested on any cancellation action on a 2,4,5-T use initiated by this Notice before the end of the 30-day notice period, the hearing will be governed by the Agency's rules of practice for hearings under FIFRA Section 6 (40 CFR, Part 164). In the event of a hearing, the cancellation action(s) subject to the hearing will not become effective except pursuant to orders of the Administrator at the conclusion of the hearings.

If a hearing on any cancellation action on a 2,4,5-T use initiated by this Notice is not requested within the applicable 30-day period and in accordance with the procedures specified above, the cancellation action will become final by operation of law.

Douglas M. Costle
Administrator

Date: FEB 28 1979

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Suspension Order

Registrations issued under the Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, 7 U.S.C. Section 136 et., seq. of all pesticide products containing 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T) for forestry uses (including site preparation, conifer release, and brush and weed control), rights-of-way uses (including brush and weed control), and pasture uses*/ are hereby suspended and the sale, distribution, or other movement in commerce, and the use of all such pesticide products for the foregoing uses is prohibited.

Douglas M. Costle
Administrator

Date: FEB 28 1979

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*/ Pasture is defined as land producing forage for animal consumption, harvested by grazing, which has annual or more frequent cultivation, seeding, fertilization, irrigation, pesticide application, and other similar practices applied to it. Fencerows enclosing pastures are included as part of the pasture.